U.S. DEPARTMENT OF COMMERCE
National Technical Information Service

PB-267 317

8th Annual National Conference on Radiation Control Radiation Benefits and Risks: Facts, Issues, and Options Held in Springfield, Illinois on May 2-7, 1976

Bureau of Radiological Health, Rockville, Md.

Prepared for

Conference of Radiation Control Program Directors, Inc.

Apr 77

PB 267 317

8th Annual
NATIONAL CONFERENCE ON RADIATION CONTROL

Radiation Benefits and Risks: Facts, Issues, and Options

May 2-7, 1976 Springfield, Illinois

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Food and Drug Administration

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U. S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

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BIBLIOGRAPHIC DATA SHEET	1. Report No. FDA/BRH-77/100	2.	3. Recipient's Accession No.

4. Title and Subtitle
8th Annual National Conference on Radiation Control--Radiation Benefits and Risks: Facts, Issues, and Options

5. Report Date
April 1977

6.

7. Author(s)
-

8. Performing Organization Rept. No. FDA 77-8021

9. Performing Organization Name and Address
HEW/PHS/FDA Bureau of Radiological Health
5600 Fishers Lane, Rockville, Maryland 20857

10. Project/Task/Work Unit No.

11. Contract/Grant No.

12. Sponsoring Organization Name and Address
Cosponsors: Conference of Radiation Control Program Directors, Inc.; Bureau of Radiological Health, FDA; Environmental Protection Agency; and the U.S. Nuclear Regulatory Commission.

13. Type of Report & Period Covered Proceedings of Conf. 5/2-7, 1976

14.

15. Supplementary Notes

16. Abstracts

This publication contains the proceedings of the 8th Annual National Conference on Radition Control--Radiation Benefits and Risks: Facts, Issues, and Options, held May 2-7, 1976, in Springfield, Illinois. Sponsors were the Conference of Radiation Control Program Directors, Inc., the Bureau of Radiological Health, FDA; the Environmental Protection Agency; and the U.S. Nuclear Regulatory Commission. Participants representing State and major local radiation control programs, as well as Federal agencies, discussed mutual radiation control programs. The formal presentations and the reports of the various task forces and workshops are included in the proceedings.

17. Key Words and Document Analysis. 17a. Descriptors

Atomic Energy Act; Bonding; Communications; Contamination; CT Scanners; Diagnostic Radiology; Emergency Response; Environment; Guidelines; Mammography; Manufacturing; Medical Accelerator; NEXT; Nuclear Power; Nuclear Medicine; Perpetual Care; Personnel; P.L. 90-602; Protection; Quality Assurance; Radiation Control; Radioactive Materials; Regulations; Soil; Standards; State Credentialing; Transportation; Waste Management; X Ray.

17b. Identifiers/Open-Ended Terms

APPROVED FOR UNLIMITED RELEASE
William L. Jackson DATE 5/16/77
WILLIAM L. JACKSON
DIRECTOR, FDA/PRDC (NTIS)

17c. COSATI Field/Group

18. Availability Statement Unlimited	19. Security Class (This Report) UNCLASSIFIED	21. No. of Pages 440
ir	20. Security Class (This Page UNCLASSIFIED	22. Price A19-A01

FORM NTIS-35 (REV. 3-72)

THIS FORM MAY BE REPRODUCED

USCOMM-DC 14952-P72

HEW Publication (FDA) 77-8021

8th Annual
NATIONAL CONFERENCE
ON
RADIATION CONTROL

Radiation Benefits and Risks: Facts, Issues, and Options

May 2-7, 1976

April 1977

Cosponsored by

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.
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ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation Programs
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and
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Rockville, Maryland 20857

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FOREWORD

The Bureau of Radiological Health conducts a national program to limit man's exposure to ionizing and nonionizing radiations. To this end, the Bureau (1) develops criteria and recommends standards for safe limits of radiation exposure, (2) develops methods and techniques for controlling radiation exposure, (3) plans and conducts research to determine health effects of radiation exposure, (4) provides technical assistance to agencies responsible for radiological health control programs, and (5) conducts an electronic product radiation control program to protect the public health and safety.

The Bureau publishes its findings in appropriate scientific journals and technical report and note series prepared by Bureau divisions and offices. Under a memorandum of agreement between the World Health Organization and the Department of Health, Education, and Welfare, three WHO Collaborating Centers have been established within the Bureau of Radiological Health, FDA:

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>
> WHO Collaborating Center for Training and General Tasks in Radiation Medicine (Division of Training and Medical Applications)
>
> WHO Collaborating Center for Nuclear Medicine (Division of Radioactive Materials and Nuclear Medicine)

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Bureau publications provide an effective mechanism for disseminating results of intramural and contractor projects. The publications are distributed to State and local radiological health personnel, Bureau technical staff, Bureau advisory committee members, information services, industry, hospitals, laboratories, schools, the press, and other concerned individuals. These publications are for sale by the Government Printing Office and/or the National Technical Information Service.

Readers are encouraged to report errors or omissions to the Bureau. Your comments or requests for further information are also solicited.

John C. Villforth
Director
Bureau of Radiological Health

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ABSTRACT

This publication contains the proceedings of the Eighth Annual National Conference on Radiation Control--Radiation Benefits and Risks: Facts, Issues, and Options, held May 2-7, 1976, in Springfield, Illinois. Sponsors were the Conference of Radiation Control Program Directors, Inc., the Bureau of Radiological Health, the Environmental Protection Agency, and the U.S. Nuclear Regulatory Commission. Participants representing State and major local radiation control programs, as well as Federal agencies, discussed mutual radiation control programs. The formal presentations and the reports of the various task forces and workshops are included in these proceedings.

OPENING SESSION

Moderator: *Robert C. Will*, Washington

WELCOME FROM THE STATE OF ILLINOIS

The Honorable Dan Walker, Governor of the State of Illinois

DEPARTMENT OF PUBLIC HEALTH'S ROLE IN RADIATION CONTROL

Verdun Randolph, Associate Director, Illinois Department of Public Health

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The Honorable George Ray Hudson, Representative, 41st District, State of Illinois and Chairman, Illinois Atomic Energy Commission

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Moderator: *Donald C. Gilbert*, Executive Director, Illinois Department of Public Health

Panelists: *Terry Lash*, Natural Resources Defense Council, Palo Alto, Calif.

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Charles Mayer, Vice-President, Tri-State Motor Transit, Co., Joplin, Missouri

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Moderator: *David K. Lacker*, Texas
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Gerald M. McDonnel, M.D., Chairman, Committee on Computed Tomography and Energent Imaging Modalities, American College of Radiology and Department of Radiology, Hospital of Good Samaritan, Los Angeles, California

REPORT ON FEDERAL RADIATION PROTECTION ACTIVITIES - PART I
William J. Dircks, Assistant Executive Director for Operations, U.S. Nuclear Regulatory Commission

REPORT ON FEDERAL RADIATION PROTECTION ACTIVITIES - PART II
William D. Rowe, Ph.D., Deputy Assistant Administrator for Radiation Programs, Environmental Protection Agency, Washington, D.C.

REPORT ON FEDERAL RADIATION PROTECTION ACTIVITIES - PART III
John C. Villforth, Director, Bureau of Radiological Health, Food and Drug Administration, Department of Health, Education, and Welfare, Rockville, Maryland

WELCOME FROM THE STATE OF ILLINOIS

The Honorable Dan Walker
Governor of the State of Illinois

Thank you very much Mr. Brunner, Chairman Will, Representative Hudson, ladies and gentlemen. I am delighted to be here this morning to have this opportunity to welcome you to the State of Illinois, what we like to call the "Land of Lincoln." We think we have a very wonderful State, but then I am sure that the representatives here from other States have the same kind of pride. We are located, as you know, right here in the Midwest. I must tell you one little story to assure you that I think I have a pretty good understanding of this State. I first learned it really about 5 years ago. When I first ran for the office of Governor, I decided to learn the State by walking it and walk it I did--a total of 1,197 miles over a period of 4 months. My feet are never going to let me forget the exact number of miles. For those of you who are not really familiar with the topography of the State of Illinois, I am here to tell you that it is not as flat as you think it is.

I learned firsthand and the hard way the boundaries of our fair State. I learned that Illinois is bounded on the east by the State of Indiana; it is bounded on the south by the sovereign State of Kentucky; it is bounded on the west by the States of Iowa and Missouri; and it is bounded on the north by Mayor Richard J. Daley. I had occasion just recently to relearn that lesson.

Seriously speaking, as one of the very real beneficiaries, as a citizen, of your work, I want to thank you for the leadership you have exercised in developing radiation control regulations at all levels of government. You and I know that the public is, unfortunately, not too well aware of your diligence. But I know this, the public does want and the public is entitled to effective radiation control regulation. We live, and I hardly need remind anybody in this room of this fact, in an area of pervasive and rapid technological change. In this atmosphere issues often become clouded. But issues like nuclear power generation, transportation of radioactive materials, use of radiation in medicine and industry, and the disposal of radioactive wastes are very crucial--not just for us--but more importantly for the public we serve. We simply cannot allow these issues to be obscured; that I believe is one of the greatest challenges faced by this conference.

We have made radiological technology work for us, but, we must make sure without a shadow of a doubt that the public safety is protected 100 percent of the time. We have a duty to make sure that the public fully understands that it is being protected at all times, for if they are not aware of this, and if they do not understand it, the public will surely resist with even greater strength in the years ahead the development of nuclear energy.

Illinois, our State, has a very large stake in your deliberations. Just a few miles away from here at the University of Chicago, the nuclear age was born. Thirty years later, Illinois is the nation's largest nuclear producer. We have over 8,000 industrial/medical radiation facilities; we have one of the large United States radioactive waste burial sites; and we have some of the the nation's largest manufacturers/distributors of nuclear material. Because we do have such a large stake in radiation control regulation, we have substantially increased the activities of our State regulatory agencies; we have tried to take a lead role in innovating programs. We have promoted new approaches to regulation, including medical and dental dose limits. We are especially proud of our

Radiological Assistance Plan--a uniform approach to emergencies. Now I know and you know that this is just the beginning; we are going to go further.

In January of this year, I created the Division of Nuclear Safety, by Executive Order, to consolidate all of the State's radiation control activities. Much of the credit for these innovations goes to our Director of the Department of Public Health, Joyce Lashof; the Chief of our Division of Nuclear Safety, Gary Wright; and Phil Brunner whom you have already heard of, Chief of the Division of Radiological Health. They all recognize the depth of public concern about the effectiveness of radiation control measures. I can assure you that they have a very deep commitment to ensure that public safety is protected. They regard their commitment as a challenge; they regard it as a great public trust. They have my full support, and you gathered here have my full support. Together we can meet the challenges in this difficult area; an area that, as I have said before, is of such great concern to the American people.

Finally, I have an official proclamation here that I want to present to your Chairman. I will not read all of the "whereas" language. I will come right to the conclusion. "Therefore, I Dan Walker, Governor of Illinois, proclaim May 2-8 Radiation Control Week." I welcome the distinguished scientists and other interested persons upon whose judgment and expertise much of our future depends and trust again that they will have a most rewarding and enjoyable stay in our capital city. I have already issued this proclamation, and now I will present it to your officials.

Again, welcome to the "Land of Lincoln." For the sake of all of us, and I do mean all of us; may your stay here be a very productive one.

DEPARTMENT OF PUBLIC HEALTH'S ROLE IN RADIATION CONTROL

Verdun Randolph
Associate Director, Illinois Department of Public Health

I am happy to tell you that the Governor has been personally interested in and has supported an increase in our staff, and it was upon his insistence that we now have a new Division of Nuclear Safety in our Office of Consumer Health Protection.

I am here today, not because of my position, but as a substitute for Dr. Lashof, the Director, who had to be in Chicago at a meeting today. On behalf of the Illinois Department of Public Health, I want to personally extend a warm welcome to you from the Midwest, from Illinois, and particularly from Springfield. We were pleased when your conference chose our State for the radiological health program to host your annual meeting. At the Department, we will do our best to make your stay with us enjoyable; hopefully, this annual meeting will turn out to be the best that your conference has ever had.

I would like to begin my remarks by acknowledging the Department's appreciation of the hard work and the cooperation given to us by sponsoring Federal agencies. During my tenure with the Department of Public Health, I have always been impressed by the close relationships between State and Federal radiation control personnel. I can tell you that that type of relationship does not exist in some of our other programs. Perhaps that is what points up the good relationship that we do have in radiological health. While we may not always see eye to eye on every issue, I believe the key to your conference success is a willingness to discuss differences and to reach decisions in an open-minded way. It is because of this spirit of cooperation and success that the Department was pleased and honored when you decided to come to Illinois.

As the Department of Public Health, Illinois also has been vitally interested in and has supported our radiological health program. Beginning in 1957 with a law that required the registration of all ionizing sources of radiation, we have progressed to a comprehensive radiation control effort encompassing the areas of regulation promulgation, field inspection, nuclear power plan surveillance, radiation user education, radioactive materials licensing, radioactive waste supervision, and radiological emergency response.

The Department currently administers four State statutes dealing with ionizing radiation and a State law which requires the registration of laser sources. Due in large part to support from our State administration, from our Department Director, and from the Illinois Commission on Atomic Energy, our radiation control effort has been recently expended to two divisions--the Division of Radiological Health, headed by Phil Brunner and the new Division of Nuclear Safety, which is headed by Gary Wright, one of our nuclear engineers.

I would like to digress momentarily and tell you about our early start in the radiological health program. We started many years ago with two engineers--Bob French, whom some of you may recall, headed up the program. We started doing some fallout research, and we did some investigation on the Chicago and Sanitary Ship Canal by putting in some isotopes to see if we could find them; and we never did. We started environmental monitoring around Dresden about 2 years before the first spade of dirt was turned. At that time the State Atomic Energy Commission was called the Commission on Atomic Power. We worked very closely with that commission; they were the sponsors and instrumental in developing our first registration law. As a matter of fact, the Commissioner wanted a registration law right off the bat; we did not think that we were smart enough or experienced enough to handle a registration act. We asked if they would give us just a registration law and let us work with that for 2 years to see if we needed regulation. Of course, at the end of 2 years we decided we did, and they sponsored the law that gave us authority to register and to develop regulations. Subsequent to the law, the Commission was renamed the Illinois Atomic Commission, and we have continued to work very closely with that commission.

The Division of Radiological Health currently has 23 professional and 3 clerical personnel, and the Division of Nuclear Safety has 6 professionals and 1 secretary. Although we were unable to finalize an agreement State status, the Department has expanded personnel in the very important area of licensing radioactive materials not under Federal jurisdiction. This is one area in which we felt totally inadequate control was being exercised in our State. Thanks to the support from our Department administration, the executive and legislative branches, and the Atomic Energy Commission, we were able to amend our Radiation Protection Act to include licensure requirements for this very important radiation control program.

Other areas of Department activity which I think deserve particular mention are: (1) our promulgation of regulations for medical and dental dose limits (I understand this will be discussed in detail by Maury Neuweg of our staff on Tuesday morning) and (2) radioactive materials transportation for which we have promulgated a new regulation that will be discussed by Phil Brunner during the session on Friday morning. We are presently considering a technician licensure bill. A draft of this legislation is out for professional society comment. With the mood of the legislature on additional licensing of professions, I do not think this is the year that the measure will be looked upon too favorably. I hope in the future, though, that we will be able to reconsider negotiating an Agreement State status with the U.S. Nuclear Regulatory Commission.

I am sorry that Dr. Lashof was unable to be here today, because I think her enthusiasm for the need for radiation control would have brilliantly shown through in her welcoming remarks. I am pleased to be able to say that the Illinois Department of Public Health has probably never had a director who was more vitally interested in furthering the cause of radiation protection and taking an active personal interest in this area. So on behalf of the Director and the Department of Public Health, welcome to our State, and I hope you have a successful week.

THE ROLE OF THE ILLINOIS COMMISSION ON ATOMIC ENERGY

The Honorable George Ray Hudson
Representative, 41st District, State of Illinois
and
Chairman, Illinois Atomic Energy Commission

It is certainly an honor to be here this morning. I, too, would like to say welcome to Illinois to each and every one of you. We are most pleased that you have chosen our great State as the location of your meeting this week. We hope that you will take advantage of any free time you may have to look around and enjoy some of the history connected with Springfield in general. I know your schedule is going to be tight; you are going to be busy. But, if you have a chance to get as far out as New Salem, you may visit Lincoln's old home restored, the restored State Capitol Building, what we call the Old State Capitol Building here in Springfield, Lincoln's home, his law offices, and even the old railroad station from which he gave that famous farewell to Springfield and his friends speech that many of you have read.

My task here this morning is to tell you a little about the role of the Illinois Commission on Atomic Energy. As Commission Chairman, I feel rather inadequate to talk on the subject that I know you are more versed in than I. I am not experienced nor schooled in the nuclear field, but as mentioned earlier, I am a State legislator and the elected Chairman of our Commission.

The Illinois Commission on Atomic Energy is one of the oldest Commissions in Illinois State government. It was first organized in 1955, and at that time was called the Illinois Atomic Power Investigating Commission. From 1955 to 1960 the Commission operated under this title. In the fall of 1960 the Commission was designated as the Legislative Commission on Atomic Energy. The Commission structure is as follows, and it has not changed too much over the last 20 years. There are four members appointed from the General Assembly--two of these are appointed by the Speaker of the House and two by the President of the Senate. The Commission is non-partisan; at present the legislative members are equally divided, with two Republicans and two Democrats.

In addition to the legislative members there are 10 other public members, all appointed by the Governor for terms of 2 years. The 10 members are from the following professions: two citizens representing industry; two representing labor; two representing science and technology; two representing medicine and health, one representing the insurance industry; and one representing the legal profession.

Also serving as ex-officio members of the Commission are the following directors of key departments of State government: Dr. Joyce C. Lashof, Director of the Department of Public Health; E. Erie Jones, Director of the Emergency Services and Disaster Agency; Dr. LeRoy P. Levitt, Director of Mental Health; Robert J. Williams, Director of Agriculture; Donald A. Johnson, Director of Labor; Joseph Pisciotte, Director of Business and Economic Development; Dr. Richard H. Briceland, Director of Environmental Protection Agency; Harvey N. Johnson, Jr., Director of Law Enforcement; Marvin S. Lieberman, Chairman of the Illinois Commerce Commission; and Langhorne Bond, Secretary of the Department of Transportation. I believe that you will agree that this group represents government, industry, science, and the general public. I might mention to you that just recently, within the past year, the Illinois Commission on Atomic Energy has engaged a full-time director. He is with us here today, and that is

Hap Day, known to many of you. We feel we made an excellent choice when we selected this gentleman to be our Director.

My subject is the role that our Commission has in State government today. I think I must give you chapter and verse, so to speak, of exactly what the Illinois statutes say. I then will talk for a few minutes on what we have done in the past and conclude by telling you a little of our present projects and programs.

In accordance with the Illinois statute, the Illinois Commission on Atomic Energy shall have the power to and shall investigate the economic, social, health, and technological impact of atomic energy resources and related facilities on the citizens of this State and any other issues which are related to the purpose of the Commission. I am not an attorney, but I believe you will agree with me that under that charge we can become involved in every segment of the nuclear society. Not only does the authority exist for this involvement, but the need for such involvement exists in our State as well. Illinois now has seven commercial reactors operating and an additional eight in various stages of construction. By 1985, approximately 45 to 55 percent of all the electrical energy produced in Illinois will be by the nuclear process. I am told by our Executive Director that no other State has a program of nuclear power equal to that of Illinois. In addition to our nuclear power plants, we have two of the largest national laboratories in existence--Argonne National Laboratory and the Fermi Laboratory at Batavia, Illinois. We also have two of the largest drug companies in the United States involved in the manufacture and distribution of radioactive isotopes for medical purposes. We have the largest uranium-conversion plant in existence, located in the southern part of this State and operated by Allied Chemical Company. A low-level burial ground is located in Sheffield, Illinois. In addition, there are over 40 industries in Illinois that are directly or indirectly involved in the nuclear business. I could give more details, but the point is Illinois has a large commitment to the nuclear program; in the next few years several billions of dollars will be spent in this State on nuclear programs and projects. We are contributing our share to Project Independence by providing low-cost abundant electrical energy to our private citizens. Also, additional benefits to our citizens are being realized by supplying this type of energy to business, industry, and government.

This Commission has been active in many ways in the State of Illinois, but I will not bore you with a recitation of past history. I do believe I should mention a few of the more important issues in which the Commission has been involved either directly or in a supportive position. It was in accordance with the Illinois Atomic Energy Commission's recommendation in the 69th General Assembly in 1957 that a Bureau of Radiological Health was established in the Division of Sanitary Engineering, Department of Health. In the 70th General Assembly, the Radiation Installation Registration Law was passed, and was strongly recommended and supported by our Commission. Several other recommendations were made during the 70th General Assembly--one of those being a ban on shoe-fitting fluoroscopes in the State of Illinois. There are a few other programs in Illinois from the past that I believe I should mention too. As far back as 1960, the Illinois Commission on Atomic Energy was recommending to the General Assembly that changes be made in the Workmen's Compensation Act and the Occupational Diseases Act. The Commission was also very instrumental in putting through planning to place Illinois in a position of leadership in educational endeavors regarding the peaceful uses of atomic energy. We are very proud today of the University of Illinois and Northwestern University for the programs they have for students that desire to enter the nuclear program. Time does not permit us to discuss all the various bills and statutes that have come about since 1955 when this Commission was first organized.

In closing I would just like to tell you what is happening now with our Commission. In the last session of the General Assembly, the Commission proposed an Electrical Facility Siting Act that included both fossil and nuclear power plants. The proposal met with strong opposition because of the concern relevant to the rights of eminent domain. After several hearings in the House, the bill sponsored by the Chairman of the Commission at that time, Representative Samuel C. Maranos, and myself, was withdrawn from further consideration. At this time it is being rewritten and studied, and will probably be reintroduced in the 1977 session of the General Assembly. Also introduced by this Commission last year was House Bill 1815, proposing new regulatory powers for the State in the transportation of all types of hazardous material. This, too, is a highly complex issue that is taking a great amount of time for hearings. The bill at present is in the Study Committee, and it is my understanding that it will leave that Committee and be reported out for floor debate in the near future. When I say near future, I do not mean to imply the next few weeks, or even perhaps this session, for you may be aware this session of the General Assembly in Illinois will deal mainly with budget matters, revenue, and other considerations that are deemed emergencies by the leadership. But, as far as the Hazardous Materials Bill in Illinois, I believe we will have a good one passed in the future. And I am sure that it will serve to further protect the health and the property of the citizens of this State.

At the present time two very important studies are being done by some very competent members of our Commission. Two months ago, two subcommittees were formed and were given the green light to dig as deep as needed for answers and conclusions to some very vital issues. The first committee is being chaired by State Senator Robert W. Mitchler. The members of his committee include Director Harvey N. Johnson, Jr., of the Department of Law Enforcement; Director Richard H. Briceland of the Environmental Protection Agency; Secretary Langhorne Bond of the Department of Transportation; and Mr. John Greanias, who is the legal member of our Commission. Their program is to make a complete investigation of the physical security of fixed nuclear facilities and the transportation of certain shipments of radioactive material. At the conclusion of their investigation they will make a complete report along with any recommendations they feel necessary. If any recommendations require legislative action, a bill will be drafted and sponsored by this Commission.

The second committee is chaired by Dr. Philip Gustafson, a public member of the Commission and also Vice Chairman of this Commission. Assisting Dr. Gustafson is Dr. Joyce Lashof, Director of Public Health; E. Erie Jones, Director of Emergency Services and Disaster Agency; and two of our public members, John Henry Kleine, who is a former legislator; and Donald Spatz, a member of the Commission, representing labor. This subcommittee is to investigate and report with its recommendations on nuclear safety and radiological emergency assistance.

Let me make one thing clear if I may. We are not looking into radiological assistance to reinvent the wheel. We know we have a good program in this field. Certainly, the people in this State involved in nuclear matters are aware of our radiological assistance team. They have been called upon for just about any type of incident you could name. They have been rushed by State aircraft to some of our nuclear facilities to investigate certain abnormal occurrences. They have used helicopters to reach isolated areas. Frequently State police cars have been used to assist this team. Many people are involved in our radiological response in Illinois, and a great amount of training has been provided.

A year or so ago we had a large plane crash just outside of the City of Springfield. Our radiological assistance team was called upon to assist in a three-day mission of searching for radioactive material. Over ten different departments of State government assisted Mr. Phil Brunner and his team during this accident. They were personally complimented by the United States Air Force Commander at the scene for their professional approach to the problem. But, certainly no assistance team can do the task assigned to them without a great amount of cooperation from other departments, agencies, and commissions. I would be derelict in my duty if I did not say at this time that the offices of emergency services, law enforcement, transportation, and several others have always joined hands with the public health team in answering these emergencies.

With such a good program, why, then, do we have a subcommittee investigating nuclear safety and radiological emergency assistance? It has been prompted by the everchanging technology, the demand by certain groups for a better program, and our own desire to know that we are getting the very best for our people here in Illinois.

I would like to close, ladies and gentlemen, with a quote by Dr. Joyce Lashof, Director of the Illinois Department of Public Health. In the 1975 Biennial Report of the Illinois Commission on Atomic Energy, Dr. Lashof made the following statement:

> "Radiological health has come a long way since the first report of the Atomic Power Investigating Commission, and with the support and assistance of the Commission on Atomic Energy, the radiation protection needs of all Illinois citizens, be they patients, radiation workers, or members of the general public will be amply served and assured."

Again, my good friends, representing here this morning at least the Illinois State Legislature, I want to welcome each and every one of you here, to tell you how glad we are to have you with us, and I bring you our sincere heartfelt wishes that your stay here will be a happy and most productive one. God bless you all.

ACCOMPLISHMENTS OF THE CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS

Robert C. Will
Chairman
Conference of Radiation Control
Program Directors, Inc.

On the agenda, the subject of this presentation is listed as "Accomplishments of the Conference of Radiation Control Program Directors." In summary, these are twofold: The Conference survived this last year and we made it to Springfield. I truly had my doubts.

On behalf of the Conference of Radiation Control Program Directors, Inc. -- one, incidentally, of four sponsors of this Eighth Annual National Conference on Radiation Control, I want to express our thanks to you of the Land of Lincoln, the city of Springfield, and the community of the government of Illinois and, of course, the supporting Region V Federal personnel. We appreciate your hosting what we know will be another great ingathering or regrouping of the troops who skirmish daily on the battlefronts of radiation regulation, control and protection.

To many of you, the first reaction to a meeting in Springfield did, in fact, raise somewhat of a question of risk. Already, we are seeing the benefits of this fine facility, a gracious host, and the lack of distraction from the fleshpots that one finds in those unnamed wicked cities to the south in which we have met previously.

I can't help but recall the reaction to my invitation to host this conference in Topeka, Kansas some years back. Topeka???.....Kansas??? There are many benefits and many delights from meeting in the Topekas and the Springfields. So, enjoy!

Of course, don't lose sight of Seattle in 1977.

Benefit vs. risk: Certainly not the newest catchword in the radiation game; rather, one which has stood up well over the years. Facts, issues, and options: The very meat of why we are here -- to present the facts, discuss the issues, and weigh the options.

To this end, our program chairman, ex-secretary/treasurer, and now chairman-elect, Jerry Parker, has engineered - with the able assistance of Jim Miller, Bob Augustine, and Shelly Schwartz - what has to be the most challenging program in which we have been priviledged to participate. Thank you, too, gentlemen.

These are critical times in our chosen discipline. One frequently finds himself at odds with himself on the issues of nuclear power, mammography, waste disposal, mining and milling, the regulatory process itself, just to name a few. At times it is difficult to stay on balance. The pressures from self-interest, from political, from anti-, and from even pro-groups, to say nothing of our Federal overseers, tend to become intolerable at times. Many of us are not, by nature, politically oriented. But responsible to the political we must be. The regulatory process is, by its very nature, political. Most of us are forced to play the game to a greater or lesser degree at home.

But here, at this forum on radiation control, we have no need for politics, or lobbying, or policy setting. And that is good. We are thus free to discuss our problems on a peer basis, without the spectre of budget effects, organizational shifts, or searching inquiry into our every utterance or activity for hidden meaning. For 5 days we can listen freely, discuss freely, disagree or agree freely, and even rant and rave freely, without fear of repercussion. Here, we are speaking and acting for ourselves. And that is good.

Before I go on to the activities of the Conference during the 1975-76 term, I would like to touch upon some areas in which radiation programs may need help. Really - nothing new. First, how do we handle the ever-increasing burden of the previously unforseen and almost overwhelming tasks that are being laid upon us? Specifically, emergency planning and response as well as the burgeoning environmental surveillance programs resulting from activities which are licensed but not under our jurisdiction? Or evaluation of procedures and techniques, such as mammography, which tax our expertise and certainly do little for our relationships with the professions? How do we resolve the question of duplication of efforts and the confusion evidenced by jurisdictional disputes among the Federal agencies -- EPA, FDA, NRC, OSHA, to cite some with whom we interact daily? Or, consider the long-range impact of the Federal performance standards. What about waste and transportation? Or, how can we handle the updating of our expertise in ever-increasing new technologies in the face of the virtual elimination of Federal training programs, coupled with declining budgetary support at the local level? Most of us are hanging on. But somehow, I don't believe we have yet felt the full impact of the budgetary crunches. I don't think the deterioration of Federal radiation protection support has shown up in the statistical picture -- yet.

About many of the items I listed, you may say: Those are not your problems. My reply: how many GAO reports have you read lately?

All of which brings me to the overriding concern of the Conference of Radiation Control Program Directors, Inc., for the conference year 1975-76: The contract. Parenthetically, I quote from the Book of Job: "Why me?"

Hyannis closed on a happy note. We were a corporation, there would be a contract jointly shared by the three sponsoring agencies for services received upon which we could base a clear-cut budget. The Conference would handle all of its business affairs. We were off to a new lifestyle. In August, the Executive Committee met in Rockville to put the contract proposal into final form. Then the Executive Committee met in Bethesda in October to polish up the finalized proposal. Then Hot Springs in November to make additional changes and adjustments in the proposal and start the wheels turning toward Springfield. Then to Phoenix; no comment. And now, here we are in Springfield, by the grace of God and a letter of intent. Again, why me?

However, all has not been entirely bleak. Before leaving Hyannis, it had been determined that 17 task forces, committees, or liaison/representatives should be carried over into the 1975-76 year, some on a very limited or standby basis. In Rockville, another 8 groups were organized or appointed in accordance with the recommendations made by workshops at Hyannis, or as needs had developed in the interim. My semi-annual report contained in the Conference newsletter in January set forth these activities for your review.

Thus, to update, let me summarize the activities, post-January, thereby achieving my charge to display the accomplishments of the Conference.

We will hear the results of the task force on naturally occuring and accelerator-produced radioactive materials (NARM) tomorrow. This was an outstanding effort underwritten by the Bureau of Radiological Health.

The task force on measurement of program effectiveness as related to radioactive materials has presented us with the first potentially workable approach to this problem that I can recall. My regret is that this hardworking group got so little feedback from any of us.

The task force on NEXT has, with little support, managed to add to the already remarkable efforts this group put forth in the past.

The various sub-groups on the parts of the Suggested State Regulations have answered their charge -- to update these on a continuing basis and to retain their now dynamic nature.

The bonding and perpetual care group has continued to investigate the possibilities for accomplishing this increasingly important facet of facility licensing.

The task force on natural radioactivity contamination, faced with budgetary restrictions, still made initial inroads into this problem.

Finally, the task force on radiation measurments is well on its way toward assuring, through NBS support, that the State programs are entering a new era of quality control.

On the less encouraging side, the task forces on credentialing, program criteria, and personnel dosimetry were inactive. Again, this was due to budgetary restrictions -- no fault of the members.

Most of the ad hoc and regular committees, as well as the liaison representatives have, some at personal expense, kept abreast of the situations which they were asked to monitor or resolve.

I want to expressly mention the efforts of Margaret Reilley, on establishing far better liaison with the Federal task force on emergency response planning than I was able to do.

The former Radiopharmacy Advisory Committee, now part K of the model regulations, met with local and national representatives of virtually every facet of the practice of pharmacy in Seattle in November. Rapport between the professional pharmacists and the regulatory personnel was outstanding and the basis for a good working relationship in the future was established.

As for unscheduled activities during the year, these include a Canadian-United States meeting in Ottawa on emergency reponse. Sherwood Davies represented the Conference at this initial meeting.

Jim Porter ably represented the Conference at TEPRSSC meetings during the year. Ed Bailey, Jim Montgomery, and Dave Lawson have attended prototype emergency response training courses and critiqued them for suitability to State program needs.

Acting on a request from Mr. Lafleur, NRC, I recently asked members and staff in Oregon, Kansas, and Pennsylvania to join with Aubrey Godwin in evaluating the proposed adaptation of existing civil defense instrumentation for purposes of emergency response. I was particularly pleased to see that my friends in Kansas -- Dave Larson and Jerry Allen, and Leon Mannel, State CD Radiac Officer, came through in their inimitable fashion.

A short time ago, I attended an NRC-Western Interstate Nuclear Board Exploratory Symposium on waste management regulation. Al Hazle, Colorado, Russell Rhodes of New Mexico, and Bill Horton of Nevada also attended. I shall discuss the Symposium with the Executive Committee and the Waste Management Task Force. There is a need for much more State program input than was evidenced in Denver.

I have had preliminary discussions with Dr. Tom Carlisle, BRH-MRAC, and Peter Wooten, in Seattle, and John Villforth via telephone on matters pertaining to mammographic screening. Initial steps toward forming a working task force composed of radiologists, physicists, and regulators were discussed.

The Executive Committee met informally with Commissioner Gilinsky at the time of the meeting of the Executive Committee in tandem with the Agreement States Meetings.

Phil Brunner acted in behalf of the Conference at the Mid-Year Health Physics Symposium in Denver.

I'm certain that I have omitted some items of interest, however, I would call your attention to the fact that many speakers, both Federal and State, who will appear here in the next few days have coordinated their individual efforts with members of the Conference, if not the Executive Committee.

What I have attempted to emphasize in this review of 1975-76 is that the Conference is a viable force. The Conference is a cohesive force -- a focal point in the regulatory process. But, Conference or no, we, the State Control Program personnel must make the regulatory process work. And to quote Commissioner Rowden speaking to the WINB last June, "There is no use having a regulatory process if the end product isn't effective."

Now in closing may I publicly thank all of you for your efforts in behalf of the Conference, including those who could not be here and your staff personnel without whose assistance the continuing processes of the Conference could hardly survive. A special public thanks to my own clerical staff who worked hard, above the call to duty, and to my supervisors who put up with me during the year. Lastly, to my wife who suffered, as have chairmen's wives before her, from the erratic, ill-tempered behavior inherent in this job.

To paraphrase the words of the old Brooklyn Dodger fans -- "Next year in Seattle."

PANEL DISCUSSION
WASTE MANAGEMENT AND TRANSPORTATION ASPECTS OF NUCLEAR POWER

Moderator: Donald C. Gilbert
Executive Director
Illinois Department of Public Health

Terry Lash
Natural Resources Defense Council
Palo Alto, California

Charles Mayer
Vice-President, Tri-State Motor
Transit Co., Joplin, Missouri

E. E. Voiland
General Electric Morris Operation
Morris, Illinois

Marion Anderson
Projects Director, Public Interest
Research Group in Michigan

DR. LASH: In my view, after 30 years of large-scale experience with the nuclear fission process and over 20 years of commitment to the commercial nuclear power industry, there still is no acceptable means for permanently disposing of long-lived radioactive wastes. There certainly is no facility available now. Indeed, there is no acceptable documented plan for the handling of the high-level radioactive waste. This lack of adequate planning in the waste management program is responsible for a very large degree of public opposition to nuclear power, and I think rightly so. The informed public is well aware of past inadequacies in the handling of governmental waste and of the problems that have developed, and continue to develop, in the commercial sector. The problems in this area are both technical as well as institutional.

I would like to give a couple of examples of the types of situations that concern the public. We have heard Hanford mentioned earlier; I fully realize that the technology used in Hanford is not the technology that will be used in the commercial sector in the future. Hanford is showing us the fallibility of institutions to manage waste and the problems caused by ineptitudes of individuals. In particular, a couple of years ago there was a leakage of 115,000 gallons of high-level waste from one of the tanks at Hanford; this leak went on for about 50 days. The serious question is, why did the leakage of high-level waste occur for 50 days without being detected and corrected? The reason was a very simple management mistake. There are two tank farms at Hanford. Associated with both tank farms are forms to be completed by the people who check the level of the waste in the tanks. For one tank farm the forms allowed the inspectors to see the previous day's reading and make a direct comparison between previous and present levels, noting any significant changes. In the tank farm where the leak occurred, however, the tank farm operator had a form which did not contain the previous day's reading; each time he took a reading of the level in the tank, he had no direct comparison to make. The comparison of readings had to be done by another management person. This first management person, who is supposed to make this comparison, apparently was overworked and the paperwork just built up on his desk. Therefore, he did not make a comparison and, therefore, did not realize that a leak was taking place. This went on for some 50 days before the quality control office, way down the management stream, realized that there was a problem and blew the whistle. I would like to emphasize that this management foul-up was not caused by the Government. We cannot blame the Federal government's ineptitudes on this one. It was ARHCO, the Atlantic Richfield Hanford Company which is the operator of the management facilities under contract with ERDA. In summary, a simple administrative mistake in improperly designing a form led to a very major release of radioactivity.

We also heard earlier, and we see statements, that this leakage of material has not resulted in the escape of radioactivity into the biosphere and has not hurt anyone. While I have no evidence that the material has reached the groundwater table, I feel certain that there is inadequate monitoring of the leaked material. We are uncertain, in fact, whether or not any significant amount has reached the water table. In any event the real question is, what is the fate of that material over its toxic lifetime, which is several hundred years at least?

In terms of commercial waste there are a number of things which disturb the public. There exist about 600,000 gallons of high-level waste produced by the Nuclear Fuel Services Plant, the only commercial plant that is operated in this country. This waste is contained in a carbon-steel tank near ground surface. What is the plan for handling that waste on a permanent basis? There isn't one. Currently there is no plan to convert the waste to glass, to put it into a salt bed, or to do anything else in particular with it. This is one of the reasons why the plant cannot begin licensing for expansions. The Battelle Northwest Laboratory has prepared a report for ERDA, which has now been published by the Nuclear Regulatory Commission (NUREG-0043), analyzing alternative processes that may be used in the handling of those 600,000 gallons of waste.

Some of the straightforward processes, such as calcine or converting the waste into a salt cake, cost on the order of a hundred million dollars or perhaps even up to five hundred million dollars. It is my understanding that the material recovered from the processing of the irradiated fuel that produced this waste may be valued at only twenty million dollars. These are the kinds of figures which do not give confidence to the public that we have this technology well in hand.

Furthermore the Battelle report states, "All potential alternatives will require successful completion of research and development programs before they can be implemented." Thus we may not apply the so-called "available technology" characterization to these wastes. The report clearly states that the research and development needs are in addition to current ERDA programs, which are, in fact, assumed to provide much information applicable to managing existing NFS waste. I believe this is a clear example that we are not at a stage that permits direct use of available technology; considerable research has to be accomplished yet.

Industry says that they are not proceeding with solidification facilities because of regulatory uncertainty. There may be some justification in that statement; however, I think there are, indeed, still problems in the technical aspects of the processes themselves. Commercial wastes have much higher burnups than the wastes that have been solidified in research programs and at the Idaho National Engineering Laboratory. It is my understanding that some experiments raise serious technical questions about the usefulness of the technology used at INEL. In any event, we are faced with the fact that the NFS plant and the Bainwell plant, which is largely completed except for its waste solidification and plutonium conversion facilities, are apparently unwilling to commit their own financial resources to build the waste solidification facilities for new waste. Both plants appealed to ERDA for the government to build the waste solidification facilities and to demonstrate to industry that high-level commercial wastes can be converted into a suitable solid form. This means we still need more research and demonstration. We are not at that stage where we can literally use available technology.

There have been other problems in the commercial sector that bother members of the public. I think the situation at Lyons, Kansas is one of them--where at least the "reactor people" of the AEC were prepared to go ahead full steam for the repository at Lyons, only to be turned around later because of problems that developed at that particular site. To us it seemed there was more concern about the appearance of having solved problems, rather than actually solving problems.

A similar situation may have occurred at Carlsbad, New Mexico, where one site was selected on a preliminary basis. Two test wells were drilled and both wells indicated that the site was suitable. It is my understanding that ERDA was prepared to go ahead and develop the site as a pilot repository. However, geologists involved in the actual program recommended that a third well be drilled. After drilling, a brine solution was found some distance below the horizon where the pilot repository would have been located. The brine solution raised enough questions that they have now gone approximately 5 miles away from the initially selected site. Drilling is to begin at this new site in the near future. While there is optimism on the part of industry and government that this operation will prove successful, we are far from knowing whether that is the case. We do not know what other problems may develop at the new Carlsbad site. One of the problems is that we do not have detailed criteria for determining the acceptability of a site once we test it. For instance, what level of water in the formation is acceptable? And what level of potash contamination is acceptable? There is a wide range of questions that will have to be answered regarding the Carlsbad site. To repeat, we simply do not have the detailed criteria, now, for determining when a site is acceptable. I think that problems like these lead members of the public to believe that we have not solved the waste management situation. What they are asking for is not necessarily a moratorium on nuclear power, as much as demanding that there not be a headlong rush into the rapid development of nuclear power in light of the problems.

I believe there is also recognition that past safety checks on the Government's actions regarding radioactive wastes have not worked. In particular, I refer to the National Academy of Sciences, which has had various committees concerning radioactive waste management for a long time. In 1966, an NAS committee wrote a report which was not well received by the AEC; it was critical of some of AEC's programs. What happened was that the committee was then disbanded. I do not know all the reasons why that NAS committee was disbanded, but it appears to the public that the occurrence had a direct relationship to the critical report written by the committee. A new NAS committee has now been formed, and all indications are that it will begin to function properly as a scientific safety check on the ERDA program.

The peer review system which works in many parts of science is not working well regarding nuclear power, in general, and radioactive waste management, in particular. There needs to be more publications in the accepted scientific literature so that independent scientists can review the material and verify scientific accuracy. It is not good enough from the public's point of view for national laboratories and consultants to be publishing internal reports that do not receive peer review on the outside.

Another check that has not worked well is the Joint Committee on Atomic Energy. It has simply not done its homework with regard to radioactive waste management. A more telling recent example, perhaps, is the failure of the JCAE to hear scientists critical of the so-called Rasmussen Study for the nuclear reactor safety study. It is incredible to me that this important joint committee in Congress failed to have even one scientist critical of the Rasmussen Report present testimony before it. This was called to the attention of the committee recently when the three General Electric engineers testified before them; the committee has now put out a press release asking the public whether or not they should have such testimony. I know that several letters have been sent saying that the committee should, and I hope that the committee members will hear such testimony.

Let me end by making some suggestions. First, I think it is important that we slow down any rapid commitment to nuclear power because of the unsolved problems in radioactive waste management alone. I think the Federal Government and various agencies have to work more closely with citizens' groups. Technically competent people from these groups have to be placed on task forces and sent copies of technical reports. Upon inspection of any Battelle Northwest Laboratory report or Oak Ridge National Laboratory report, you will see a distribution list at the back. The list includes industry; it does not include any representatives of citizens' groups. That kind of situation has to be corrected. I have tried to correct it personally by writing to the ERDA; but ERDA officials refuse to send out free copies of these reports. I think that is a shame, and it does their whole program a great deal of harm.

Concerning the States, I think there are two areas in need of correction. First, although there is no direct authority pertaining to high-level radioactive waste management, I think it is incumbent upon you to review carefully the Federal program and to be able to answer questions that the citizens in your State have in great detail. I think it is incumbent upon you to comment on the Technical Alternatives Document which will be coming out shortly that reviews the long-term options for handling radioactive waste. I think it is important that when the programmatic environmental impact statement for the ERDA program comes out in the spring of 1977, each and every State that either has a commercial nuclear power reactor now or will have one in the future comment on the EIS--stating what the position is of that State on the adequacy of the Federal program.

Regarding areas where the States have direct responsibility (this pertains primarily to the Agreement State Program, principally), I think you have to take a serious and searching review of whether or not the State programs are adequate now; whether or not you really have the capability for protecting the environment and the public health over the hundreds of years that those materials remain potentially dangerous. If you do not have such capability now, seek ways either to develop that capability or give that authority back to the Federal Government and ask that they do an adequate job.

I think there is reason for concern on the part of the public to suspect that in some regards these programs are not adequate at the State level.

MR. VOILAND: In order to discuss the management of nuclear wastes it is perhaps advisable to first review briefly the nuclear fuel cycle and identify the source of nuclear waste that is of concern to this panel.

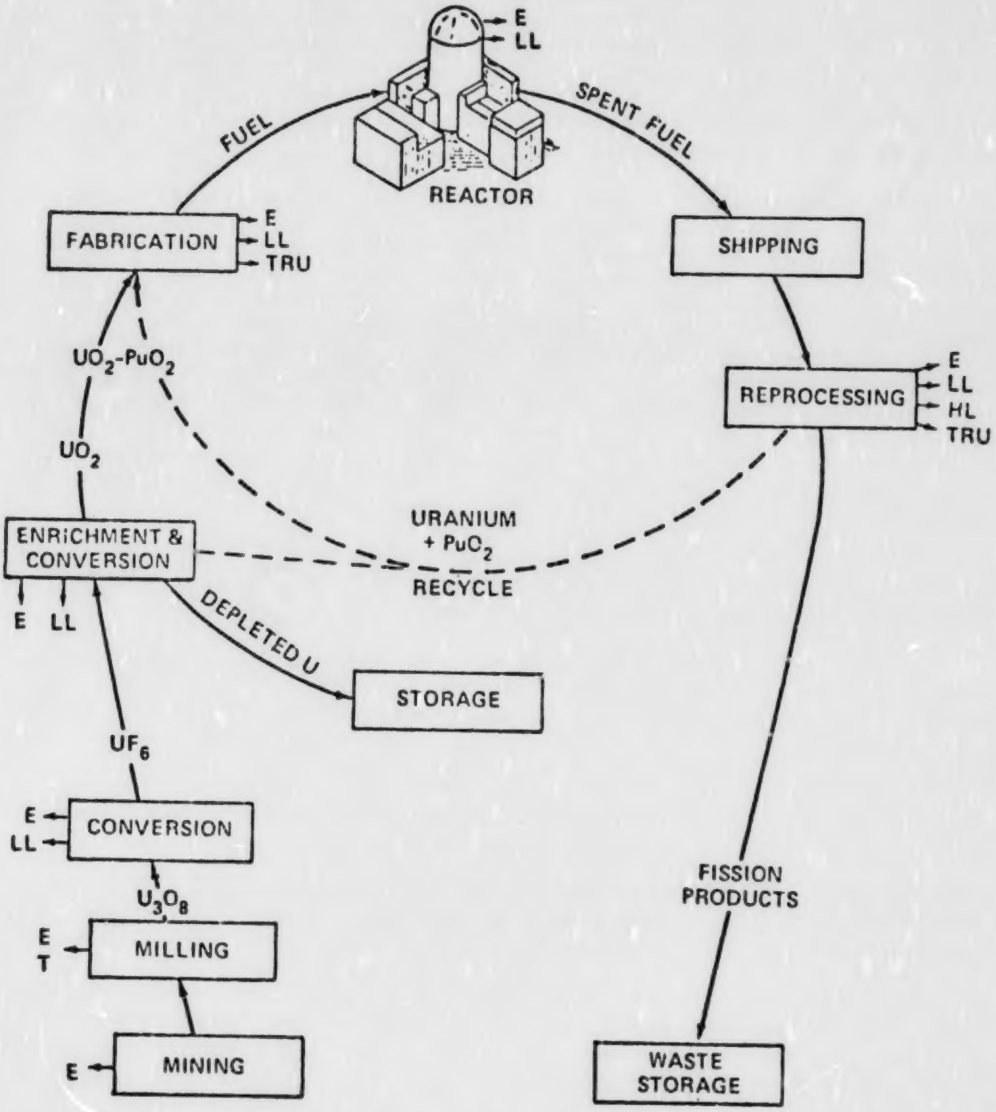
The generation of electricity from the atom is completely to its generation from a fossil fuel. Both methods use steam-driven turbo-electric generators. The fossil fueled plant uses the heat from burning coal, oil, gas, wood, or refuse to form the steam; the nuclear plant uses the heat from fissioning uranium and plutonium. Unlike the case of the fossil plant in which the combustion products have no usable energy content; the spent uranium fuel does have "unburned" uranium and "burnable" plutonium. The potential for these materials to be recycled through a nuclear steam supply system (a nuclear reactor) gives rise to the concept of the closed fuel cycle.

The nuclear fuel cycle is outlined in figure 1.

The mining and refining operations are typical of operations used for recovery and purification of other metals.

The enrichment process is unique to the nuclear field and is used to increase the uranium-235 content from 0.7 percent to from 3 to 4 percent. (Uranium-235 is the fissionable isotope.)

COMMERCIAL NUCLEAR FUEL CYCLE *
AND TYPES OF WASTE GENERATED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LEGEND

E - RELEASABLE IN EFFLUENTS
HL - "HIGH LEVEL" RAD WASTE
LL - "LOW LEVEL" RAD WASTE
T - MILL TAILINGS
TRU - TRANSURANIUM - CONTAMINATED RAD WASTE

* From ERDA briefing on Fuel Cycle Budget, January 28, 1976.

Figure 1

Fuel fabrication involves conversion of uranium hexafluoride - the material used in the enrichment step - to one-half inch long ceramic pellets of uranium dioxide. (As an alternate mixed oxide, natural uranium dioxide containing 3 percent plutonium dioxide, can be used.) These pellets are sealed into 10- to 12-foot long thin-walled metallic tubes which are asembled into fuel elements (also called bundles or assemblies) containing roughly 50 to 200 rods depending on reactor type. The ceramic pellets are of the consistency of a dinner plate, densified to about the theoretical density of uranium dioxide (10.9) and are physically stable and chemically inert.

After fabrication the fuel is "burned" in the reactor where part of its mass is converted to heat during the fission process. (It is perhaps appropriate to digress for a moment on the enormous amount of energy produced by a typical present-day base-load power plant. Typically a utility plant--whether nuclear or fossil fueled--is rated at about 1000 megawatts of electric power. Such a plant in the Commonwealth Edison northern Illinois service area serves all the electrical needs of about 850,000 people including supporting industrial and commercial activities (1). To produce this much power for 1 year requires about 3,000,000 tons of coal or 10,000,000 barrels of oil, but only about 35 tons of enriched uranium. The small amount of uranium used accounts in large measure for the economy of the fuel cycle, because of reduced handling and transportation costs, and--as we will see later--makes possible the efficient management of the high level radioactive wastes.

After the fuel is no longer useful in the reactor it is discharged and stored under water at the reactor site for at least 150 days to allow short-lived radionuclides--and heat output--to decay.

In this closed fuel cycle the spent fuel is subjected to fuel reprocessing whereby the unused uranium (and plutonium generated while the fuel is in the reactor) are separated from the fission product wastes. Currently no commercial reprocessing plant is operating in the United States (or the Western World).

The uranium can be reenriched by recycle to the enrichment process or by addition of plutonium in a fuel fabrication facility.

The term "nuclear wastes" includes a variety of materials, but of principal concern is the high-level waste produced in fuel reprocessing that includes essentially all of the intense radioactivity separated from the spent fuel.

The composition of the high level waste before any treatment is shown in table 1. It consists principally of radioactive and nonradioactive fission products, some actinide elements, process chemicals and corrosion products (from process equipment and fuel hardware).

The enormous amount of radioactivity requires an extremely high level of control; first, to prevent exposure of people and other living creatures to the very intense penetrating radiation and second to assure that the radioactive materials are not ingested or inhaled. This control is what is included in the the term "waste management."

The objectives of a high-level waste management program are inherently simple:

(1) To prevent release of radioactive materials to the biosphere, and
(2) If release should occur, to assure that the release does not exceed acceptable concentration levels.

Table 1. High-level waste composition annual output - 100-MW_e reactor(2)

Metallic Component	Weight (Kg)	Megacuries
Iron	35	
Manganese	4	
Chromium	7	
Fission Products	1000	
Plutonium[a]	1	135
Americium	0.1	0.02
Curium	1.1	
Neptunium	15	0.6
* * * *		
Total New Weight	1 Te	
Total Gross Weight	5 Te (as Glass)	
Total Gross Volume	64 cu. ft.	

[a] Assumed 0.5 percent loss in reprocessing.

(These principles are no different than those used in management of any activity that might result in a dangerous outcome. One takes appropriate effort to prevent the unwanted occurrence and also takes additional precautions to limit the consequences.)

Having stated the waste management objectives, the obvious question is "How well can we expect to meet them?"

To answer this question we can examine how high-level waste management has been approached in the past, how well it has worked, how it has evolved, and what its current status is.

Historically, large quantities of high-level waste were first produced at Hanford in 1944 and were produced continually as a byproduct of four different separation processes until about 1970. The management of this type waste--which in terms of current waste management concepts were quite primitive--simply involved the neutralization of the aqueous first cycle acidic waste stream and storage of the resulting alkaline slurry in underground carbon steel lined, reinforced concrete tanks ranging in size from 50,000 to 1,000,000 gallons. Although a half a dozen major leaks were experienced and considerable amounts of radioactive nuclides escaped, the waste was confined to the vicinity of the tanks and therefore the objective of keeping the biosphere unpolluted was accomplished. Close to 100 million gallons of waste were at one time stored in this fashion at Hanford, with about 150 tanks involved (3,4).

At Savannah River, similar carbon steel tanks were used, but, because of the less compatible storage environment, were placed in partially steel-lined concrete vaults to provide better control in the event of leaks.

Over the operational lifetime of these sites, tanks have been improved both by design and by better fabrication techniques. The resulting "tank-within-a-tank" provides a very high degree of protection against leakage(3).

That long-term storage of wastes as liquids was undesirable, was recognized at Hanford in the 1950's, and R&D programs to contend with the problem were initiated. The occurrence of leaks stimulated effort, and a plan was conceived to reduce the potential mobility of the radioactivity by evaporation of the water and solidifying the wastes in the tanks. At the present time about 80 percent has been solidified and the volume occupied by the salt cake is 29 million gallons(5). About 22 million gallons still exist as unsolidifed waste. The moist solid is being dewatered to leave only interstitial water as a residue. The combination of residual decay heat and air purge will ultimately lower water content to very low levels. New equipment acquired in the last few years has accelerated the rate of solidification, which--for current inventory--should be complete in 1977. Because heat transfer in solids is much worse than in water, it was necessary to largely remove the long-term heat producing radionuclides strontium-90 and cesium-137 in order to control internal temperatures. These are stored separately as contained solids.

Waste from the only United States commercially operated fuel reprocessing facility, the Nuclear Fuel Services plant in New York State, has also been stored as a liquid, pending conversion to solid. Most of the waste was stored as alkaline slurry in carbon steel tanks; however, some waste, derived from the processing of thorium targets, was stored as a homogeneous acid solution in stainless steel tanks. Storage as acid waste has the advantage of reducing extraneous chemicals and hence the volume of both stored liquid and resulting solid waste.

At the AEC/ERDA operated Idaho Calcination Pilot Plant, a fluidized bed process has been used for over 10 years to convert all the high-level wastes from naval and test reactor fuel processing to a dry granular solid that is stored in underground reinforced concrete vaults. (A modification of this technique was intended for use at the Midwest Fuel Recovery Plant at Morris, Illinois.(4))

Direct conversion to a solid--particularly one of high chemical stability obviously reduces the mobility of the waste and better meets the objectives of a waste management program. The in-tank solidification program at Hanford is producing a solid that in the semi-arid climate of the site, and with the precautions taken, provides assurance that the material will not migrate from its location. There is continuing evaluation of the need for further immobilizing this solidified waste and investigation on processes for doing so are continuing. The calcined waste (at Idaho) is inherently more stable than the in-tank solidified waste and, because of the small volume and type of storage, can be recovered for disposal if that becomes appropriate.

Obviously the desirability of a very inert material that will remain intact upon exposure to environmental agents is self-evident. This was early recognized by the AEC and, from the mid-1950's, waste solidification processes for power reactor wastes were being developed under AEC sponsorship. These studies culminated in a major demonstration program at Hanford in the period 1967-1970. This program included operation of the Waste Solidification Engineering Prototype (WSEP)--a full-scale demonstration plant having a capacity for processing high-level waste equivalent to that from a 300 MTU fuel reprocessing plant.

Thirty-three runs were made in this prototype using Hanford production wastes enriched in rare earth, strontium, and cesium fission products so as to better simulate power reactor fuels. Three processes were demonstrated and products including calcines, phosphate glass, and borosilicate glass were produced. These were stored in stainless steel cylinders typical of those designed for commercial fuel reprocessing plant use. Since the time of production, these materials have been periodically cored and tested for chemical stability particularly for the leach--or dissolution--rate by water.

In a recent conversation with Mr. A. M. Platt, Manager of Nuclear Waste Programs at Battelle-Northwest, I learned that these follow-on characterizations have disclosed only slight deterioration of properties in the borosilicate glass but that the phosphate glass--because of temperature induced devitrification--has worsened in leach rate by a factor of 1000. One might argue that 5 years of testing is trivial in terms of the storage requirements. Recognizing this, accelerated tests using curium-244 have been made. By incorporating this nuclide in glasses of the same chemical composition as those made from high-level wastes, radiation damage equivalent to that from 1000 to 3000 years of storage of commercial waste-glasses has been accumulated. The results of characterization tests show little deterioration of the material. Additional tests to devitrify a simulated glass--and thereby alter its physical characteristics and chemical stability--have not produced a material of less desirability. The product resembles Corning's "Pyroceram," a very inert material.

Continuing programs with the WSEP are aimed at optimizing the composition of the borosilicate glass--to further reduce the effect of temperature and radiation on leach rates--and preparing test quantities of glass from authentic commercial fuel reprocessing wastes.

Historically, then, the demonstrated technology of waste treatment has evolved from storage of neutralized aqueous solutions to incorporation of the wastes in a chemically stable solid which is resistive to environmental attack.

By placing the "glassified" waste in inaccessible storage (disposal) so that shielding from the penetrating radiation is provided and re-entry to the biosphere is precluded, the full objective of waste management can be met.

Current thinking is that this isolation can best be achieved by storing stainless steel canisters of the "glassified" waste deep in geological formations of known long-term stability (millions of years). There are a number of such formations suitable for this purpose; salt deposits being perhaps the most favored at this time. Burial in salt formations was proposed for disposal of wastes by a National Research Council - National Academy of Sciences Advisory Team in 1955 and studies with spent fuel elements at Lyons, Kansas have demonstrated, in part, the practicality of this type of storage(3).

Disposal to a stable formation would require only minimal surveillance to prevent inadvertent drilling. A site without access to ground water is obviously preferred, but the nonleachability of the glass would provide an additional measure to reduce the consequences of release from the site if water were to encounter it. Release would be very slow; dilution, and the chemistry of the actinides--the only radionuclides of significance after a few hundred years--would result in activity levels comparable to natural radioactivity in certain areas.

From a consideration of radioactive decay and the waste management time frame, it is possible to gain some insight into the control of radioactivity by disposal of "glassified" waste to stable geologic formations. In Table 2 is shown the radioactivity (in curies) at 150 days, the minimum time of transfer from the reactor to reprocessing plant; 10 years, the maximum time allowed before the solidified waste is transferred to ERDA for storage or disposal; 100 years, a conservative lifetime for stainless steel; and 1000 years, a conservative lifetime for glass. Noteworthy items from this table are:

- After 10 years, radionuclides of less than 1 year half-life are essentially gone. (Residual activity is due to 285-day Ce-Pd-144.)
- After 1000 years only actinide elements exist and constitute about 0.001 percent of the original (150-day) activity.

- Plutonium is a relatively minor constituent and control for several hundred years is based on strontium-90 rather than plutonium or actinides.

Table 2. Radioactive decay of high level waste from annual output 1000 $MW_{el.}$ reactor

	Total	Short[1]	Long[2]	Actinides	Plutonium
150 days - Ci	175×10^6	110×10^6	65×10^6	0.6×10^6	0.02×10^6
- %[3]	100	63	37	0.4	0.01
10 years - Ci	10×10^6	0.01×10^6	10×10^6	0.07×10^6	0.01×10^6
- %	5	0.01	5	0.04	0.006
100 years - Ci	1×10^6	2	1×10^6	7000	500
- %	0.6	-	0.6	0.004	0.0003
1000 years - Ci	1000	0	0	1000	150
- %	0.008	-	-	0.0007	0.0001

[1] Fission products with half-life less than 1 year.
[2] Fission products with half-life exceeding 1 year.
[3] Expressed as percentage of total radioactivity at 150 days from reactor discharge.

If the plutonium estimated after 100 years decay were to migrate 50 feet from the repository position and be uniformly distributed throughout this 100-foot sphere, it would be only about 10 nCi/g, or at a level comparable with some naturally occurring radioactivity in soil. Ten nanocuries per gram has also been proposed as a guide for surface burial of low-level transuranium wastes.

It would thus appear from these considerations that incorporation of high-level wastes in borosilicate glass and disposal to stable geological formations at depths of a few thousand feet would pose little risk to living creatures.

(Although there is not very much actual information on the long-term migration of fission products from the site of disposal, there is at least one very interesting example in the discovery in 1972 in Gabon, Africa of the residues from an ancient reactor--about 2 billion years old--that operated for possibly a million years. It is noteworthy that the stable rare earth fission products--which have comparable chemistry to transuranium elements--are still intimately associated with the deposit of depleted uranium. The presence of depleted uranium was, of course, the first clue to the existence of this natural reactor which is so old that the plutonium had all decayed away!(8))

I am fully convinced that the present-day technology of converting wastes to inert materials and storing them in stable geological formations is an available technology and one that fully provides protection for the biota of present and future societies.

That this technology is not being used is simply due to the lack of decision on the part of the Nuclear Regulatory Commission in officially approving it.

The current regulation of the Nuclear Regulatory Commission (NRC) is that high level wastes may be held as tanked solutions for no more than 5 years from time of origin at the site and for no more than 10 years as solidified wastes.

At the end of the holding period they are to be transferred to a Federal facility for retrievable storage or other disposition.

Decisions have not been made as to the details of the Federal waste management system to be used and the industry--because of lack of guidance as to the construction of expensive conversion facilities--had been unwilling to proceed. In my discussion with Mr. Platt, he commented that the document ERDA-76-43, whose publication is very imminent, will state that the technology indeed is available, that minor engineering on the storage/disposal details is required, and that there is no reason to further delay the decision on high-level waste management.

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3. "Final Environmental Statement, Waste Management Operations, Hanford Reservation, ERDA-1538" USERDA, December 1975.

4. "Management of Commercial High Level and Transuranium Contaminated Radioactive Waste, WASH-1539," USAEC, September 1974, p. 1,2-4ff.

5. Personal Communication, H.P. Shaw.

6. "Recent Discovery of a Prehistoric Nuclear Reactor in Republique Gabonaise," G.A. Vendryes, CEA, France, undated, ca. 1972.

MR. MAYER: And Chicken Little said, "The sky is falling" and all the chickens ran into the fox's den for protection. This venerable fable came to mind as I sat listening to a somewhat emotional individual expressing views in support of proposed legislation to regulate the transportation of nuclear materials.

Over the past several months, I have attended a number of such hearings which are being held in an increasing number at State, county, and city levels.

Some of these hearings have been for the purpose of determining if a need exists to regulate nuclear transportation. Others have dealt specifically with proposed regulations.

What disturbs me is that appearing before these legislative committees are housewives, grandmothers, school teachers, students, lawyers, and various incenerary individuals who obviously do not have meaningful technical knowledge on the subject. I have found that their comments are often emotional outbursts of rhetoric parroting viewpoints of other individuals, much of which is questionable with regard to factual information.

For several years many States have been interested in the transportation of hazardous materials over their roads, particularly in the area of emergency response. As an outgrowth of this interest, several States now have good programs in effect which can deal quickly and effectively with a nuclear emergency should one be encountered.

The aura of urgency and impending doom which seems to grip certain facets of our society is perplexing. We have a 30-year experience time frame from which to evaluate nuclear transportation safety. The transportation record to date is good! There have been no injuries or deaths due to the radiological nature of the many shipments that move throughout our country. This is not happenstance. It is the result of effective safe shipping practices initiated many years ago when the nuclear industry was in its infancy.

Over the years, regulations have been promulgated to increase safety and drastically reduce risk factors. I think the container design criteria established by the Atomic Energy Commission in 1963 under Federal Regulation 10-CFR-71 was a most significant step in transportation safety. This program is carried on today by the Nuclear Regulatory Commission, the Energy Research and Development Administration and the Department of Transportation.

There have been several accidents over the years involving radioactive material shipments, but there has not been a single incident of a Type B package failure.

I should mention at this point that a Type B package is for the larger quantities of radioactive materials that pose a hazard above certain defined levels and are considered those that present serious radiation or toxic hazards.

Transportation incidents on record to date involving the release of radioactive material were either Type A or exempt packages. These incidents involved primarily radioactive pharmaceuticals or radiography sources and presented no significant hazard.

Many studies have been made regarding the safety of nuclear transportation by such competent organizations as Sandia Laboratories in Albuquerque, New Mexico (SAND-74001), Pacific Northwest Laboratories of Battelle Memorial Institute (BWL-1846), Holmes & Narver, Inc. of California (EPA NSS 8191.1), and the National Academy of Sciences (ERDA-8). These studies in substance concluded that there is no undue risk to the public and if a transporation accident should occur that resulted in the release of radioactive material, the results would most likely be relatively small exposure to individuals near the accident.

Then why are the housewives, mothers, grandmothers, school teachers, students, lawyers, bakers, and candlestick makers so uptight over the transportation of nuclear materials. In my opinion, it's because not one, but several Chicken Littles are constantly screaming, "The nuclear sky is falling." To illustrate my point, let me read a couple of items which I think you will find interesting:

The Evening News, Newburgh, New York -Tuesday, March 16, 1976.

"A flat bed truck hauling waste down from a Vermont nuclear plant had a "fender bender" accident 100 feet from the Toll Plaza during the usual afternoon rush. Hillard Arline, of 44-1/2 Landers Street, Newburgh, had just come off the ramp and entered the rush hour traffic. Suddenly the truck and car came together.

"Arline's vehicle suffered a foot-long scratch and dent."

The headlines that accompanied that little article: "Atomic Waste Truck Crashes!"

Commentary by Jack Anderson - Station WAVA Radio Syndicated, Washington, D.C. - March 18, 1976 - 12:40 p.m.:

"Did New York City barely avoid a major nuclear disaster?

"I'll have an exclusive report in a minute. This is Jack Anderson in Washington.

"New York City may have just barely avoided a major nuclear related disaster, and only by sheer luck. Last Monday a tractor trailer carrying forty thousand pounds of nuclear rod resin collided with a car on the Newburgh-Benson Bridge over the Hudson River. Rod resin is a material used to demineralize deadly radioactive waste produced by nuclear reactors.

"Fortunately, the collision was only a minor one, but it could have been catastrophic. Why? Well, highly vulnerable casks loaded with lethal radioactive materials are being transported by truck throughout many densely populated urban areas. In this case, local police investigating the accident were unaware of the potential dangers. But New York scientific experts told us that if the rod resins had fallen from the bridge into the Hudson River two hundred feet below and broken open, the entire city's supply of drinking water would have been threatened. To avoid a major threat to public health, dredging crews would have had to dig up the Hudson River for at least half a mile to assure that none of the rod resin contaminated the city's water supply."

Unless I have been grossly misinformed, in no way does New York City or any of the communities thereabouts obtain their drinking water from the Hudson River. You can well imagine what impact this must have had on listeners who are not knowledgeable with regard to radioactive materials. When the memory fades, people aren't going to remember that a fender bender took place a hundred feet from the Toll Plaza of the Newburgh Bridge. They're going to remember the headline which screamed, "Atomic Waste Truck Crashes." And the imagined horrors which the words "atomic" and "crashes" connotate. As for Mr. "Don't Bother Me With Facts" Jack Anderson, he had done his part too, and I need comment no further on that.

There are a lot of other Chicken Littles. Take for example the PIRGIM Report entitled, "Fallout On the Freeway." An AEC staff review summarized this report as follows:

The PIRGIM report takes out of context information provided by AEC (1) in its generic environmental survey on transportation (WASH-1238); (2) in letters from AEC staff to PIRGIM; (3) in various speeches and reports by the AEC; and, (4) in reports by the General Accounting Office in the area of transportation of nuclear materials. Combining this information with inaccurate technical conclusions concerning releases of radioactive cesium under assumed accident conditions, the report concludes that shipments of spent nuclear fuel present "perilous hazards" for the population along transportation routes.

I would like to cite an example of the type of inaccuracies that are found throughout this report. On page 21, under the heading "A Choice of Two Evils" the report states:

"After conversations with the Michigan State Police, the Ingham County Sheriff, the Michigan Department of Public Health, and two drivers of a truck carrying nuclear materials, the following conditions of highway transport for casks carrying radioactive waste become clear:

(1) "Drivers receive no special training for carrying nuclear waste."

(This is totally inaccurate. Drivers do receive special training for the transporting of nuclear cargoes.)

(2) "Drivers do not have radiation detectors with them, nor have they been trained in their use."

(Totally inaccurate. Drivers are trained in the use of radiation detection instrumentation and are equipped with GM counters and film badges when transporting high-level radioactive waste or spent fuel. Tri-State Motor Transit Co. has spent in excess of $12,000.00 for instrumentation to be used for this purpose.)

(3) "Trucks are not inspected, not even their brakes."

(Again, totally inaccurate. Trucks are inspected each time they arrive at a terminal. Brakes, airlines, lights, horns, windshield wipers, tires, cargo tie down, tractor and trailer frames, etc. are all carefully inspected, noted on a standard inspection form and signed by the individual making the inspection. This is done each time a unit arrives at a terminal, and if the unit is in two or more terminals in a single day, it is inspected each time.)

(4) "The drivers take whatever routes they choose."

(Totally inaccurate. All shipments, nuclear or otherwise, are routed by the Joplin office. Drivers are never allowed to take whatever routes they choose.)

(5) "Drivers do not check with the Michigan State Police to find out about road conditions."

(Drivers often check with State and local police when weather conditions are such that they may encounter impassable or dangerous road conditions.)

(6) "There are no check points along the route."

(Again, totally inaccurate. Transport units carrying nuclear cargoes are on what we term Code 6 orders. This means that the driver must report to the Central Dispatch Office in Joplin, Missouri every 6 hours or less and give his location and other pertinent information relative to the move.)

Further on page 21 of the report we find the following: "When the reactor supervisor at Michigan University, Dr. Bruce W. Wilkinson, ordered some used (irradiated) fuel rods, the following occurred:

"Our fuel rods came from San Diego. The truck went to Joplin, Missouri. They parked the truck in a terminal in Joplin on Friday night with the cask on it. Then they went home to see their families on Sunday. When the cask arrived, the outside of the casks were contaminated. In some places they were two to three times as high in contamination as they should have been according to AEC minimum standards.

"One wonders if any little children in Joplin had been fascinated by the big casks and touched them, thus becoming contaminated with radioactivity."

Let me describe briefly the Joplin terminal facilities in which this unit was parked. The facility occupies 410 acres and represents an investment exceeding $1,000,000. One hundred and fifty acres have been improved with a 7-foot high security fence topped with 6 strands of barbed wire. The entire facility is illuminated at night with mercury vapor floodlights. Access to the facility is limited through one gate, manned 24 hours by security guards. In addition to the gate security guards, the facility is occupied with roving guards and on-duty personnel around the clock. The unit referred to in the PIRGIM Report was securely parked in a security terminal approved by the Department of Defense. One can readily see that these conditions are somewhat different than one is led to believe in reading the report, "Fallout On the Freeway."

I could talk for another hour about the Chicken Littles and what they are doing to frighten and confuse those who are not knowledgeable on radioactive materials and their related hazards. But I have to get back to the subject of regulations.

Tri-State Motor Transit Co. is not opposed to good, effective regulation of nuclear transportation. What we are fearful of is State, county, and city legislators and administrators being stampeded into highly restrictive and impractical regulations. Interstate movements of nuclear materials often traverse a series of States and overly restrictive and diverse regulations will create a chaotic regulatory situation that would impair their movement and seriously affect this country's energy needs and financially burden all segments of our society.

You, as members of the National Conference of Radiation Control Program Directors, are responsible members of the scientific community. Although there may be differing views, you do possess the knowledge and understanding to speak out authoritatively against inaccurate and misleading statements that confuse and cause undue concern. We live in a technological society. Our scientific achievements have often carried a high price in human lives and well being. We have to determine what the acceptable risks are going to be for the benefits of nuclear energy and then make the commitment. This is not new to us. We decided long ago that 55,000 lives a year are acceptable for the benefits derived from the automobile. This is also true for electricity, airplanes, boats, bicycles, you name it. The point is that Mr. and Mrs. Average American, like myself, lack the knowledge and understanding to make the decision. It will be you and people like yourselves, trained in the sciences, that will have to establish the scientific base or reference from which to determine regulatory needs and provide the guidance required to develop effective uniform regulations consistent with those needs. And in the end answer us: Is the nuclear sky falling?

MS ANDERSON: I was rather interested in the onset of the previous speaker's presentation, involving the concept that the average citizen--typified by housewives, students, professors, lawyers, and so forth, are incompetent to judge or even to discuss, apparently, the things affecting them.

In 1965 there were a number of us, 14 percent to be exact, of the American public that became a little dubious that the Vietnam War was such a cool idea. We began all the series of actions, which those of you present undoubtedly remember, that culminated in the termination of one President and the ending of a war 7-1/2 years later--the longest war in American history. We were told from the beginning that we were not experts, we were not generals, we were not colonels, and God knows we were not the Joint Chiefs of Staff; so what were we out there talking to the American public about.

The basic concept of a democracy is that the average person does know and think and can judge; it is upon that basis that I should like to discuss the concepts of transportation of radioactive wastes as a very great danger to American public. We have been told by one of the speakers here this morning that radioactive wastes and the gases which they may deport have to be isolated from the biosphere. That is quite a concept--essentially saying that we are producing substances so dangerous, so poisonous that they have to be utterly kept from the air, the water, and the soil, indefinitely; for as you all know plutonium lives for hundreds of thousands of years--that, again, is an incredible thought. Contrary to what was recently said about my report, "Fallout on the Freeway," it is a matter of fact that it has been widely accepted throughout the United States. The report has been used by Governors, by State Legislators; served as the basis of a 1-hour long program recently produced by the National Broadcasting Company of Japan; and has been sold in a number of countries throughout the world--widely regarded as a fairly standard work on the subject.

One of the reasons why I think "Fallout on the Freeway" is regarded as a fairly standard work is because of the outstanding work done by the General Accounting Office in Washington--an agency which is responsible to Congress rather than the executive branch of the Government. The GAO found a series of problems involving casks. When I started to do the work on "Fallout on the Freeway," I did not, as a matter of fact, expect to be doing a report on casks; I expected to be doing a report only on the routing of the transportation of radioactive waste through Michigan. Instead, I found out, when corresponding with the Atomic Energy Commission, that the AEC's response was that it does not make any difference what routes people take, how miserable the road conditions are in Michigan, whether or not the roads are covered with ice, or the occurrence of a blizzard. Rather, AEC feels that, "our casks are perfect and they will never open."

I take a theological as well as a political position that the works of man are not perfect. However, we found out while working with a GAO report, a considerable number of conversations with engineers at the Michigan State University and at the University of Michigan, and a number of physicists that there is a serious problem involving both the acceptance of the design and the manufacturing of casks. They are not inspected by government inspectors on general fashion while in transit on the road. The casks are essentially a large mechanical piece of equipment. When we think of casks we tend to think of something very inert, such as a wooden keg that you put beer into.

Casks carrying the fuel rods, though, are entirely different. Fuel rods are both very hot from a point of view of radioactivity and physically very hot. They have to be kept cool while in transit. Dr. Mark Ross, who worked with us throughout this report, had a long conversation with Dr. Larry Shepherd, the most eminent U.S. authority on casks and the author of "The Cask Designer's Guide." Dr. Shepherd said to Dr. Ross, There is no question that with a big water-filled cask, a gasket will malfunction or a valve will leak and the water will leak out. As the water begins to leak out, the remaining water then gets under higher pressure because the hot fuel rod inside will turn it ever faster into steam. Consequently, the radioactivity will spread over the landscape the same way, by the same route the water followed and people will become contaminated with radioactivity. Dr. Ross, and the other physicists are working with him at the University of Michigan, found that the AEC was not forthright about the entire contents of these casks. He found that AEC simply did not discuss the most lethal of the casks' contents--the radioactive cesium. In addition, he found that if an accident occurred--either involving a collision on a highway or simply a leakage of water, thus allowing radioactive steam to escape--the following number of deaths would occur in large metropolitan areas: Over a period of 25 years there would be 3,800 deaths from cancer in Boston; 4,100 in Chicago; 3,000 in Detroit; 2,700 Miami; 4,000 in New York City; 4,300 in San Francisco; and 3,400 in Washington, D.C. If the accident took place in an average populated suburb, about 700 people would die over a period of time. Cesium also contaminates the land for about 15 years, thus making it unhabitable and unfit for farming.

Our previous speaker was a little bit ingenuous in reading to you from page 21 of my report, "Fallout on the Freeway," however, what he did not read from was a case history involving one of his very own trucks, trucking out of Joplin, Missouri. This is a case history which happened when two organizations from PIRGIM (Public Interest Research Group in Michigan), volunteered to follow a truck, and I shall read to you. "On narrow two-lane roads the truck averaged over 50 miles per hour; at 2:33 p.m., outside of Mancelona, a small town in northern Michigan, on a narrow two-lane road the shoulder was below the level of the black top; the truck went into the left lane to pass a car on the curb--the driver had poor visibility. At 4:20 p.m., the truck tailgated Carol Smith's car (she was the woman driving the car accompanied by the other volunteer) and then passed them on a two-lane road. By 4:45 p.m., the truck was going over 70 miles per hour and passed a truck carrying highly flammable material, stored only a few feet away. At 6:25 p.m., the driver stopped for dinner; this incidently was not on their route, it may well be that the drivers were told the route to follow. However, we found through conversations with these drivers that they took an entirely different route as they approached the place where they like to have a lunch break. They liked the restaurant there and that's where they were going to have their dinner. Carol Smith and Mark Goldstein asked the drivers if they knew what they were carrying. They replied that they did but did not seem very concerned about the possible dangers as they left the truck running for an hour while they were eating and talking.

Now there was another accident reported at the beginning of "Fallout on the Freeway." This occurred in Stroudsburg, Pennsylvania, just a few weeks before our report was ready for publication. A truck carrying radioactive materials began a chain collision on a freeway. The accident involved 6 trucks, mostly semi's, and two passenger cars. The passenger car was not only totaled, but burned up completely. The man driving the passenger car went to sit in a police car and while sitting there with another guy unknown to him, sitting in the back, a fireman came up to him and said, "That truck over there says radioactive on it and I don't want any of my guys to go near it until I know what's in it; do you know what's in it?" And the guy said, "No, I don't know. I was driving that car over there; it's all burning up." But the guy in the back of the car spoke up and said, "Oh yeah, that's my truck." The fireman said, "What's in it?" The truck driver said, "Oh, I don't know; I'll have to get my manifest." So he looked all around, pulled out the thing and said, "Oh, it's cobalt."

I had a long talk with the driver of the truck, the driver of the car, and the State Police involved, sort of reporter like fashion, and I also called the people in Cleveland who were shipping the radioactive cobalt. The people in Cleveland who were shipping the cobalt said that if the semi had hit their truck, the cask would have opened and the situation would have been very serious. In addition they said that people within 20 feet could have sustained only about a minute of exposure without dying; the people up to a half of a mile away could have been seriously hurt, and even up to a mile away especially, I assume, if they were infants or old people.

The simple fact is that in this country we are producing an enormous amount of highly lethal material. And I think before we take the rather placid assumption that there is no reason, since we have the technology why we shouldn't proceed with it, we should argue a little thought to who's making money. I spent about 13 years on Capitol Hill and one of the very first things thought about in any kind of negotiations was, who is benefitting? Ralph Nader, as you all undoubtedly know, talks about the subject a good deal, and he has one line that struck me before I got into the subject or had really thought about it a lot myself. The concept was, how come all this American tax money and Federal research money is being taken off to promote nuclear power? Why isn't it being used to promote nonlethal sources of power; such as solar power, wind power, or for that matter, fusion power?

The reason is, I believe that nuclear power is immensely complicated; it's a highly technical thing that is very expensive, and since it is so capital intensive only very large companies can afford to put up nuclear power plants. Small companies can't afford it; small towns can't afford it; even very small cities on a whole can't afford it. Therefore the rake off on the other end tends to be considerably larger. If everybody could start, everybody meaning small companies, small towns, and so on, could put up plants involving solar or wind power, the big oil companies and the companies who own nuclear power plants simply could not go ahead and get their accustomed enormous rates of profit. So I think all of us will have to give serious thoughts to whether or not we want, as a nation--as people concerned with the health of the public--to endlessly go on piling up highly lethal wastes in forms that cannot enter the biosphere in any form; or whether we seriously want to go into the form of alternative energy which can give our people the energy that we need without storing up this enormous amount of radioactivity for our future generation.

DISCUSSION

DR. SOLON: First I would like to associate myself with the mothers, grandmothers, students, teachers, and great grandmothers whose views are very welcomed in the city of New York along with the views of senior executives of the transportation companies which transport radioactive materials.

Let me address the question to Mr. Voiland of General Electric. This question of the simulation of 4,000 years of storage in either phosphate or other glass--how was that achieved by employment of high specific activity Curium 244? The process, it seems to me, would only relate to the dose one could deliver over a short time and would ignore the question of dose dependent effects, as well as other interactions that would take place in the course of a couple of millenia.

MR. VOILAND: The simulation is not perfect at all. However, without waiting thousands or millions of years, you have to do what you can. There are accelerated temperature tests, and there are the ongoing tests of the actual glasses that have been prepared from the production wastes at Hanford. A not perfect, but not bad simulation has resulted from the knowledge of the kinetics of the process, the deposition of radiation damage in the glass, and the scientific analysis.

MR. JOHNSON: I would like to direct my question to Mr. Mayer. Perhaps your response, your presentation, was a personal vendetta type--that's the way I interpreted it. Is there a generic set of conditions, shall we say, for the trucking industry--those who are transporting radioactive materials. You say that Tri-State has certain requirements for their drivers, you have certain standard operating procedures, but does the industry as a whole?

MR. MAYER: First of all I want to make it clear that there is no vendetta; there is no judgment on my part. All I plead to you people, here today, is that let's base decisions on scientific facts; that's all. Let's base decisions in an outright, forthright fashion. The transportation industry is not classed as a nuclear industry; it does not have any provisions set on it in terms of exposure, and that sort of thing. We have established in our own company, in our company only, certain limits. We have a full-time health physicist on our staff who is the overall director of our nuclear program within our own company.

MR. AAROE: Mr. Lash alluded to a problem with the high burnup wastes that are being experienced, relatively recently I gather from what he said. I was wondering if between Mr. Lash and Mr. Voiland if this subject could be elaborated on; that is, with regard to the use of borosilicate glass or Plexiglas materials.

DR. LASH: I want to express, again, that although we are not reprocessing any commercial wastes right now, even if we were, we would not have the high burnups that are assumed in studies because reactors are not operating reliably enough to attain those high burnups; however, if the projections of capacity factors are finally fulfilled and you have the high burnups, there are problems then in terms of the different mixture of radionuclides in the fuels. This situation occurs at both reprocessing steps--in terms of the solidification that these higher burnups may cause some problems that have not been resolved. This is partly theoretical because we simply have not had the high burnup material to work with. But in talking to some people in General Electric interested in the LMFBR program, I found there may be even hotter spent fuels to reprocess. These are quite significant problems. In terms of the glassified wastes, I don't remember the total radiation exposure given. I'll leave the subject of glasses for Mr. Voiland to address. It's my understanding that while these glasses were exposed to substantial radiation, they were not greatly deteriorated. This is still in the research stage--that is we haven't mimicked what would happen if you glassified a real high burnup waste and what that does in terms of breaking down the glass structure. I think it's just in the research stage and one can't say.

MR. VOILAND: I guess you could say that, indeed, it is in the research stage, because it has not been demonstrated on a commercial fuel basis. However, the Battelle program involved the use of waste which had been enriched in radiocesium and radiostrontium. (You may recall the chart that we used here, showing that after 10 years those are the principal heat producers.) The waste solidification program and the tank solidification program at Hanford, requires the removal of radiocesium and radiostrontium in order to solidify those wastes in large volumes without having excessive temperatures. Over the years, highly concentrated cesium and strontium has been produced and that was spiked in to the standard production wastes to bring them up to levels which were actually hotter and contained more radiocesium, more radiostrontium than you would have in a power production fuel. Since there were no available commercial type wastes at that time, this was the best that could be done. I think in terms of simulation, it was very good. Those are the wastes which are cored and characterized annually.

DR. NADER: As an interested citizen I heard two kinds of statements this morning about what happened with the case of the truck from your company, Mr. Mayer, at least I heard Marion Anderson's version. Do you want to comment on the accuracy, or the inaccuracy of her statement, and if it is accurate, what action your company took to correct that situation?

MR. MAYER: I'm not certain I have any details on the particular accidents that were referred to. The occurrence in Pennsylvania, I believe, is the one you're talking about.

DR. NADER: I'm talking about the one that Marion Anderson was discussing. I think they trailed one of your trucks, and she described a big gap between what you say and what actually was.

MR. MAYER: Well that's hard for me to make a judgment on, because this charge was never passed down to us except in the form of the report itself--which we did not receive directly, we had to receive it indirectly. First of all, I might say that Tri-State Motor Transit Company tractors, are primarly in the heavy hauling business. Consequently, our tractors are geared with a transmission and rear end ratios that prohibit the truck, if the maximum RPM is 2100 RPM's, to exceed 58 miles per hour on level ground. We would have to be going down at pretty steep grade to achieve anything over that and to go to 70 miles per hour with a tractor; we would be up against the governor and cause serious damage to the engine. So I doubt very much, personally, that the truck actually ever hit 70 miles per hour--55 miles, yes, but not 70 miles per hour.

Secondly, there's been a reference to tailgating. I don't know if anybody here has had any experience in driving a truck; I have. First of all, the only way a truck can safely pass a car, if you want to call it safely is, it has to tailgate the vehicle it is going to pass before it pulls off to the left lane. This is particularly true of two lanes. Unlike the automobile, when you push down on the accelerator of a truck nothing happens--a car will accelerate immediately, a truck will not. A truck is also 55 feet long. So in order to pass, even a car going 35 miles per hour, the truck driver has to shift down if he is in those ranges; but if he's running up in the higher ranges for legal speeds, he has to get up as close as he can to the car he's going to pass, and then go to the left and proceed to pass. Now to move 55 length units past a car, takes considerable time; so to reduce the time in the left lane, he has to follow that procedure. Be that as it may, that is the safest and best way to do it.

MS ANDERSON: I'd like to make a point at this time, that PIRGIM is not engaged in attacking either the trucking industry in general, or certainly Tri-State Trucking, in particular. Our feeling is simply as follows: The casks can open under two specific conditions; one is by mechanical malfunction and one is fire on the road. All the trucking industries can give all of the directions to the drivers they want, but the simple fact is, they are dealing with human beings--human beings do what they feel like when they feel like it. This guy wanted a big dinner at the place where he wanted to eat, so the hell with the route set, he was going to eat there. The guys that put the cask together in the factory have bad days and bad nights like everybody else--like everybody in this room has had. The time is going to come that no matter how important the weld they make on those casks arc, they're going to stay out real late at night drinking; they're going to get home and their wives are going to say where have you been; there will be a big scene; they're going to get 2 hours of sleep; get up the next morning, go to the factory and say oh the hell with it, I'll do anything I feel like--I feel horrible, I have a hangover, I'm going home and go to bed.

Those are the problems we're talking about. They are the human problems; they're the same things as the management problems that the guy that got overworked. Everybody in this room has had really bad days--days you feel overworked and you simply cannot get to even the most important thing you think you have to. That's all were saying. That when we're dealing with an industry like this, even the best isn't good enough.

MR. VOILAND: I would like to make three comments here. One of them concerns the leakage of waste at Hanford. This has been bruited about in the papers for many, many years. Terry has referred to it, and everything he said was true about that 115,000 gallons. The Atlantic Richland Hanford Company gets "A for dumbness;" as they just mismanaged this situation completely. In terms of any harm to the environment however, there was no damage, no problem. The reason being is that in the early days of Hanford, and for many many years (in fact I'm not sure if they're still not doing it), the practice was to crib radioactive waste. This was a waste management judgment that was made to put liquid radioactive waste, up to a 10th of a curie per liter in the ground, storing the radioactivity by absorption on the soil. There is 200 to 250 feet to ground water. It is a semiarid country where rainfall does not reach ground water level; the 5 to 7 inches a year of rain evaporates from the surface. Lower level contaminated water actually went to the ground water and the radioactivity was monitored by wells. The annually published "available-to-anybody" environmental status of the Hanford site gives the contours of tritium and cerium and the nitrate in the ground water (see for example "Evaluation of Radiological Conditions in the Vicinity of Hanford for 1969," Editors, C. B. Wilson and T. H. Essig. Battelle Memorial Institute, November 1970 (BNWL-1505)). They are way below the MPC (Maximum Permissible Concentration). There were millions of curies of radioactivity purposely, willfully, as a management judgment put into the ground. The contribution of the wastes and leaks, although deplorable, didn't really change the risk to people from the planned disposal to ground, which has been trivial.

Secondly, with respect to the Mark Ross report, that report was based upon some suppositions. One supposition was that 30 percent of the cesium went to the voids, and that was calculated on the basis of the hottest rod in the reactors. The estimate that has been made, knowing the history of all of the rods is that about 1 percent of the cesium would be in the voids. Secondly, there was an assumption made that 100 percent would be released from the voids in the event of the accident postulated. They treat experiments where a much more violent environment existed, resulted experimentally in a 1 percent release. The AEC made a very good analysis of the Ross report, and I'll quote from their report. "AEC staff studied Dr. Ross' paper and found it to be a simplistic and shallow treatment of the subject, replete with errors of fact and assumptions." These things have a hard time getting into perspective. Sometimes you will take all of the worst conditions and say if this happens and that happens, and so on. If a large meteor fell on Chicago, there would be a lot of people killed! You have to look and see whether the risks associated with this business are really acceptable risks in terms of the benefit. And that's another story. But obviously there is a large ground for people to feel that it isn't. I got the impression that Mrs. Anderson feels that no risk is acceptable. I think that Terry feels that perhaps there may be an acceptable risk. I guess from having been in the business and worked with plutonium and with waste and managed programs of research and development, that I feel comfortable with nuclear energy. People have to make their own judgments about that, and the real problem today is to try to get the information by which to make those judgments when extremes of perspective of thought are being presented all the time. For somebody who hasn't thought and studied about this, I'll tell you, I don't know how they can make the judgment.

MR. GILBERT: We leave behind here the era of the need-to-know syndrome which is over. If you could draw one conclusion from the discussions up here, it would be that in dealing with radioactive waste in transportation and associated problems the Federal Government and State government are going to have to interface. They are going to have to communicate, and then in turn there's got to be a communication with the general public. Also I would guess I would have to say that the panel's diverse opinions represent what our democratic government is about--one can respect another person's right to have an opinion and at the same time respect his own right to disagree with that opinion.

IS THERE A RADIATION EFFECT THRESHOLD?

Albert W. Hilberg, M.D.
National Academy of Sciences, National Research Council

When Dr. Jim Miller called me in January and asked if I would be willing to come before this group again this year, I indicated my pleasure at being invited. Then, he gave me the topic I was to address. I considered for a moment and decided that I could probably give the shortest talk ever presented. The topic - "Is there a radiation effect threshold?" The talk - one word "no."

Feeling that a two-letter, one-word, presentation would not be very appropriate, I considered the alternatives: I could simply send in a large placard with the word "no" imprinted in suitable colors; I could show up here and simply say the word "no"; or I could come before you and try to explain the word "no." It is obvious that I have chosen this latter alternative. I am here to try to explain why I believe I can say there is no radiation effect threshold.

While the answer may be a simple "no," this "no" should be placed in proper perspective. One way to think of an effect is measurability. Certainly, at very low levels of exposure to radiation, a measurable effect on a total organism or tissue may be, and often is, impossible to identify. The effect on a single cell nucleus, or part thereof, may be, and often is measurable.

Another way to think of measurability of an effect is to consider the result of an effect. Again, on the presumption that a single cell may be affected no matter how low the exposure, just what will the result or manifestation of this effect be on the organ or whole body? Now one enters a spectrum of biological fact and hypothesis concerned with mechanisms of repair, immunogenesis, mutagenesis, carcinogenesis, and, not least, the genetic effects which may be manifest only as the affected gene is passed on to the next generation and future generations. (A further exposition of various theories and arguments may be found in several texts (1), (2), (3).)

It is no wonder that, while it can be stated that there is no radiation effect threshold, the practical aspects of this statement are less clear when applied beyond the cellular, in vitro, biological system. The obscurity that begins with the multicellular response to a single cell event may well lead to the presumption that there is, in fact, a practical threshold response. In a simplistic way, this may be explained as follows: If the effect is confined to a single cell and the effect is cell death, then the only response of surrounding cells may be to replace the dead cell with no further effect on the living cell population. Thus, while there was indeed an effect on a single cell, there is also no response other than simple repair; thus, leading to no discernible tissue effect--a practical threshold. There are many other mechanisms of repair and defense which may also lead to no identifiable effect in a living organism.

There seem to be at least two such examples of a practical threshold in the human: (1) development of radiation cataracts and (2) impaired fertility. Even in these instances, however, there is some real question about a true threshold.

As stated in ICRP Publication 14, "the more careful the observer, the lower the dose at which he will just be able to detect differences between irradiated and unirradiated lens." However, citing experimental work, the report goes on "...the experimental result seems to imply that there must be a threshold cataractogenic dose for irradiation of the whole lens and that subthreshold exposures of the whole lens do not lead to the development of cataract" (4).

As regards the instance of impaired fertility, we note also in ICRP Publication 14, "for normally fertile men and women, there is a threshold type of response.... For some but not all men and women whose intrinsic fertility is less than the average, there is likely to be a greater sensitivity to radiation and possibly in extreme cases some effect, however small the dose" (4).

It may be appropriate at this time to briefly review some statements concerning a radiation effects threshold. It is certainly not possible within a few minutes to do more than cite a very few reviews of the entire literature and, from them, to attempt a coherent trend of thinking.

Starting with the BEAR Reports, the Summary Report, published in June 1956 (5), contains these statements: "Any radiation is genetically undesirable since any radiation induces harmful mutations. Further, the genetic harm is proportional to the total dose."

In the section of pathologic effects, this statement appears: "Since the cancer cell is an altered type of a normal tissue cell, it has often been suggested that cancer is a somatic mutation, like a genetic mutation, but arising in a tissue cell which perpetuates the character by its growth."

These statements from the summary document of the BEAR Committee (5) deliberations were based on the known facts and research studies at that time.

During the 20 years since the publication of the BEAR Committee Summary report, it is probably safe to estimate that several hundreds of millions of dollars and untold man-years have been invested in research efforts to determine the effects of radiation on biological systems. Yet, 20 years later, the sum of all of this effort is that, while we know a lot more, we still have not changed the thrust of the statements just cited. There is still no firm evidence of a threshold effect and evidence still supports a no threshold or linear hypothesis of effects from ionizing radiation.

In the publication, "Late Somatic Effects of Ionizing Radiation," issued under the auspices of the U.S. Atomic Energy Commission in 1968 (1), we find this statement: "In what may be the best example of clear-cut experimental data, the induction of phage growth in lysogenic bacteria, no threshold was found: one ion pair per cell was effective. It is, therefore, prudent to assume that biological effects will follow irradiation however small its amount."

The NCRP in its Report 39, published in 1971 (6), states: "The presence of a threshold below which one or more of the several possible radiation effects are absent would be of great practical importance for radiation protection. Unfortunately, present knowledge does not allow a definitive judgment as to whether or not a real threshold exists...."

The same report later states: "For purposes of conservation planning, it continues to be prudent to assume a non-threshold linear relationship for dose versus effect in the region of low dose, but this does not justify the use of extrapolations to predict effects, except for gross estimates of maximum possible effects."

Going on the BEIR Report (3), issued in November 1972, there is further review and some additional statements which are pertinent to this discussion. In the section, Summary and Recommendations, there is the statement: "until recently it has been taken for granted that genetic risks from exposure of populations to ionizing radiation near background levels were of much greater import than were somatic risks. However, this assumption can no longer be made if linear threshold relationships are accepted as a basis for estimating cancer risks." Later in the same report there are these statements: "For induction of some tumors, a linear non-threshold dose-effect relationship cannot be excluded from existing data, nor can the possibility that such effects might result from sublethal injury in only one or a few cells of the body. It is unlikely that the presence or absence of a true threshold for cancer in human populations can be proved."

These statements lead to the UNSCEAR Report (7) published in 1972. Citing a few statements from this report indicates that, again, there is little or no evidence to exclude a linear hypothesis of effects of radiation:

> There have been many attempts to demonstrate the presence of an absolute threshold for radiation effects. It appears that there is a threshold for very resistant tissues since it requires doses of more than 800 rads in a single brief exposure of the exteriorized kidney to produce kidney tumors in rats and an exposure of more than 35,000 roentgens with local continuous irradiation at high dose rate to produce oesophageal tumors in mice. While it has not been disproved that there is an extremely low but slowly increasing response below these effective doses, it seems more likely that induction of these neoplasms occurs only after sufficient tissue destruction and regeneration have occurred, suggesting the existence of a threshold. For more susceptible tissues, however, the threshold, if it exists, is at sufficiently low doses to require massive, expensive experiments to determine its presence.
>
> On the other hand, the concept of a 'practical threshold' has been introduced by Evans. This concept is based on the fact that, as dosage decreases, the latency or tumor appearance time increases in some monotonic fashion such that there will be some value of the dose below which the tumor appearance time exceeds the life span. This concept is supported by the suggestion that most, if not all, neoplasms show a decreasing latency with increasing dose and that animals irradiated as adults often die of other diseases before developing long-latency neoplasms because the latency exceeds the remaining life span. However, the relationship of dose to latency varies with the end-point for determination of effect. In addition, an accurate determination of the dose at which latency equals the remaining life requires extrapolation into low-dose ranges where no data exists, which raises much the same problem encountered with the absolute threshold. Further, different values for the practical threshold result when the data are plotted on a semi-log as compared to a log-log plot. It has also been suggested that an extrapolated least-square fit to the MIT human radium data provides a better estimate (and a considerably lower 'practical threshold' dose) than the method selected by Evans. Thus, while a 'practical threshold' based on latency has some validity, it also appears to have many of the same indeterminants that plague the absolute threshold.

The arguments for threshold either absolute or practical, while forcefully resented by many investigators, are still questionable as far as absolute effects may be measured.

As a final citation of literature, articles appearing in the Journal of Radiation Research, published in Japan in 1975 (8), continue to confirm that there appears to be a linear dose-effect relationship in the development of leukemia (9) and in the development of at least two solid tumors; breast and lung (10). While the authors point out that a considerable amount of information is still to be obtained and that there is still considerable analysis to be done, the most extensively studied and cited information on human exposure experience, that of the populations of Hiroshima and Nagasaki, still continue to support the general feeling expressed over the past several decades that the linear hypothesis for radiation effects is the most prudent approach and that, so far, there is little or no reason to suspect it is not a correct approach to the problems of radiation effects and protection.

Having now given you my reasons for saying that there is no threshold for radiation effects, I believe that one must also look carefully at the implications of this statement if, indeed, the evidence allows us to accept no threshold as a fact.

It should be obvious that, if there is no threshold, then all biological systems have been steadily subjected to the effects of radiation since the beginning of Earth's time. Inherent is an exposure level to radiation which has been unavoidable and still is. This cosmic and background radiation has undoubtedly varied through time and a logical guess may be that it has gradually decreased through time, although an increase may also be postulated. Nevertheless, it is still with us and exceeds most other sources of manmade radiation as far as general population exposure levels are concerned.

Since the primary reason for believing that there is no threshold is based upon the work of geneticists and since the most probable effect of very tiny amounts of radiation is primarily manifested as a molecular gene effect, then we must accept that all biological systems, including man, have evolved subject to the radiation effect upon the genetic material.

We must also accept that, if there has been a somatic effect from the tiniest of radiation exposure then, also, all biological systems have existed and changed subject to whatever somatic effect has occu[illegible] in each generation of man. Perhaps one may then further speculate that there is a certain, as yet unknown, point of "equilibrium" that can be reached by biological systems exposed to ionizing radiation and that, somehow, this is achieved by any biological system with only those amounts of radiation identified as natural background. The problem then may be simply the issue of whether or not the equilibrium, thus established, is tilted or destroyed entirely when manmade radiation exposure, or any other type of external source of exposure such as hydrocarbons, noxious gases, etc., are added to the natural radiation exposure to which a biological system is already subjected.

In summary, since there is no identifiable threshold of radiation effects, then any amount of radiation exposure obviously will cause some effect. This effect may be totally undetectable and our present methods may be totally inadequate to identify such infinitesimal effects. The effect may be of little or no consequence to the individual exposed and may only be demonstrated through further evolutionary change, good or bad.

I would like to close my remarks with a quote from Tyron Edwards, a theologian of the 19th century (11) - a quote which I believe summarizes to a great extent the present state of affairs concerning a radiation effect threshold: "Imperfect knowledge is the parent of doubt: thorough and honest research dispels it."

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DIAGNOSTIC RADIOLOGY - WHOSE RISK? WHOSE BENEFIT?

Claire Nader, Ph.D.

A novel situation which we face today is the trend which allows the privileged few, in area after area, to make decisions for the many with little accountability and with unprecedented consequences. These circumstances create a very special responsibility for the few: to follow a strict policy that emphasizes the speedy reduction of actively harmful consequences and meticulous attention to potentially harmful consequences.

In taking the consumer's view of radiation exposure problems, I am going to emphasize the themes of responsibility, involvement with consequences, of accountability, and of the need to rediscover an old ethic that stresses prevention of disease. In today's society we can identify different types of elites, but it is necessary always to distinguish those who arouse momentary attention and are important in a limited context, such as baseball players, and those whose actions have a general and sustained impact on people. In discussing diagnostic radiology, we clearly are focusing on the latter type. In the case of medical x rays, among the few whose decisions affect the health of millions of people are radiologists and other physicians, dentists, operators of x-ray equipment, government regulators, legislators, manufacturers of equipment, inspectors, and scientists. Within this group, some have higher status than others, possess greater resources, and exercise greater power over how medical x rays are in fact managed.

In this effort the directors of radiation control programs occupy a difficult position. They and their staffs have the tough job of seeing that programs are developed and implemented so that the benefits to patients of medical x rays are increased by reducing avoidable, unnecessary exposure. Moreover, their responsibilities include the safe management of other sources of radiation; such as nuclear power plants, microwave ovens, and color television sets. But, in too many cases, responsibilities are added without adding the requisite human and material resources to carry them out. This discrepancy between responsibilities and the wherewithal to get the job done is glaring and is one of the realities associated with the role of the inspector that needs to be faced squarely. Insufficient resources significantly restrain effective performance and tells us something about the status of this role in the hierarchy of roles in the medical x-ray area.

To operate effectively, it would seem to me that radiation control program directors need at least two kinds of information. The first is technical information such as radiation effects on people, monitoring techniques, and exposures from different diagnostic examinations. The second is information about the social structure of the various interests that shape the system of control in diagnostic radiology. In other words, one needs to know who gains and who loses if changes are made in the present system of control.

The second kind of information is as critical as the first, if good practices are to replace bad practices. Nonetheless, too often conferences of this type focus on the technical aspects of a problem and ignore the human, often limiting, side. Timely problem solving, however, requires both technical and social information. The medical x-ray exposure problem is in great part a social problem; so I focus on the social information that radiation control program directors can use in strategic pursuit of their humane mission.

A number of points need to be appreciated anew--and I say anew because much of this is familiar to you. The first point is that the public dispute that surfaced almost a decade ago over the safe use of medical x rays had little to do with patient and population exposure to radiation. There was agreement that the level of radiation exposure could be substantially reduced both by training personnel in the use of machines and by manufacturing better machines. No one argued that this reduction should not be pursued. It is necessary to appreciate, however, that the dispute was basically over whether the risk from present dosage was high enough to warrant a change in the voluntary system of controlling diagnostic techniques that radiologists, physicians, and dentists have created over the years.

Lodged in the question of voluntary versus mandatory standards of control are issues of responsibility and accountability. The consequences of change involving self-correction concerned the medical community enormously. This concern was highly visible in the defensive way that representatives of the medical profession responded to criticism in the 1967-68 public debate leading to the passage of the Radiation Control for Health and Safety Act of 1968. For years they had regulated the technology and made the enforced decisions without review from others. It was understandably painful to have outsiders question the efficacy, safety, and continuance of the self-regulatory decision-making system they had set up.

A second piece of social information carrying a message for future radiation protection strategies focuses our attention on the value of outside critical review to all parts of the country's radiation control program. When the leadership of any system--especially one that is so vital for individual and public health--hides itself from public scrutiny, it can quickly become unaccountable. The dominant perspectives of what is correct become skewed; and the controllers can easily lose touch with their original mission, in the case of medical x rays, to protect patients and the population from unnecessary exposure.

Nowhere was this phenomenon more sharply evident than in the 1967-68 debate when the prevailing system of radiation control first came under severe criticism. As many of you will recall, public exposure and criticism highlighted the need for mandatory performance standards covering a number of electronic products (including diagnostic x-ray equipment). At that time public concern over the medical profession's regulation of the risk/benefit questions relating to diagnostic x rays came in the wake of public worries over defective color television sets. The critics argued that unnecessary and avoidable diagnostic exposure should be reduced for reasons of health and improved diagnostic information and, as good practice amply demonstrated, it could be reduced.

Thus, to reduce exposure critics advocated mandatory standards for x-ray equipment, licensing of technologists, and the cautious and judicious use of x rays. None questioned, then or now, the many benefits to human health of x radiation; nor did they suggest that the scope of use of diagnostic x rays be legally restricted; rather, they focused on preventing unnecessary exposure. The criticism of outsiders--health physicists, radiation control officers, consumers, and even a few insiders--constituted, I believe, the first significant public questioning of the quality of the medical stewardship. By "public" I mean debate that went on outside of technical meetings.

The medical profession did not take this criticism lightly; rather, it responded vigorously. From the medical profession's congressional testimony, three major themes shaping its thinking became apparent. After these themes surfaced it was easier to understand the almost violent reaction to any discussion of the medical x-ray question. The first theme was the unwavering insistence that the radiation hazard in medicine and dentistry is "negligible" and that the magnitude of the hazard is exaggerated by critics. The second theme repeatedly manifested distaste for a system of mandatory, legal controls that would curtail medical discretion in any way. The third theme expressed aversion to informing the public and to broadening the decision-making base allowing public participation in the cost/benefit analysis process. Nonetheless, the dikes had been pierced, and public criticism rose to such an extent that an opportunity for change presented itself.

While the medical groups moved to stem the forces of change inherent in the negative criticism they were receiving, critics sought to restructure institutional arrangements that would be more responsive to the problem of unnecessary exposure. For the medical groups, this period was a time of political crisis; their professional credibility was at risk.

Public criticism forced a long overdue assessment, and in the process created a most useful public hearing record that helped clarify for consumers what the fight was all about. A radiation control perspective, different from the medical one, emerged from a coalition of interests that shared a philosophy of prevention and sought to shift the burden of proof of the efficacy and safety of the x-ray technology onto the users of that technology. Unfortunately, the momentum of this critical review subsided for a number of reasons. These reasons provide additional pieces of social information that are central for the understanding and the development of effective radiation protection and control strategies.

First, despite its farsighted legislative initiative in 1967-68, Congress did not follow through to strengthen the legislation and to provide strict oversight as to how the law was being implemented. Lacking, then and now, was an organized public constituency to ensure substantial Congressional participation in law enforcement and amendments that would strengthen the law. As Representative Paul Rogers once remarked to me, no one is consistently knocking on his door; and the press of other legislation, especially that with a finite lifetime, assumes a higher place on his agenda of work.

The second reason for the momentum dying out is that routine attitudes and behaviors often persist despite outside provocations. The medical profession as a whole cannot be said to be in the forefront of the movement to cut unnecessary exposure; I say "as a whole" because there are a few, of course, who are always receptive to better ways of practicing medicine. The substantial variations of exposure that currently exist for any one examination are a clear case in point. Such variations indicate that uneven, sloppy practices continue despite educational efforts to improve diagnostic x-ray procedures. Note, for example, a booklet entitled "X-Ray Examinations, A Guide to Good Practice" issued in 1971, jointly by the American College of Radiology and the FDA's Bureau of Radiological Health, in which physicians were informed that in some x-ray examinations as much as two thirds of the exposure added nothing to the diagnosis and "therefore may be unnecessary." By the way, why the equivocating language here, a consumer wonders.

Third, unlike the unorganized patient community, the medical interests with substantial organizational and other resources at their command comment regularly with the Bureau of Radiological Health and make their views felt. Bureau officials generally believe that they can accomplish more by maintaining "good working relationships with the profession," to quote one Bureau official. However, close working relationships of a consensual nature between the regulator and those to be regulated can subtly compromise the independence of the regulators. Almost imperceptibly the regulators begin to assume the objectives and timing of those whose behavior and actions they are supposed to assess. We have observed this in looking at how bureaucracies operate in other problem areas. Some Bureau officials recognize that one result of working closely with the profession is that, "We may be doing a disservice to consumer education efforts. We have done virtually nothing in the consumer/patient area." The special alliances with the medical profession produce at least psychological captivity and an ambivalence in the Bureau regarding who its first client is.

Another factor that affected the momentum to do something about unnecessary exposure and unnecessary x rays was that press coverage peaked in 1968, but since then has declined precipitously. As the sense of urgency surrounding the 1967-68 Congressional hearings died, it became apparent that the medical perspective of risk/benefit survived as a dominant force in the process of administering and strengthening the 1968 Act.

However, some restraints were placed on medical discretion. It is useful for future planning and actions to note these restraints because they indicate opportunities for introducing some measure of accountability into the system of radiation control. One restraint comes in the form of the 1968 Radiation Health and Safety Control Act itself in that it required performance standards to be set for new x-ray equipment. Another is found in State efforts such as those of Illinois to establish patient exposure limits for certain radiographic examinations in a systematic attempt to reduce unnecessary exposure. The fact that several States now require licensing of radiologic technologists, and others are moving toward licensure, and that California requires physicians to qualify in radiation protection principles is also a hopeful sign.

Yet another restraint on medical discretion in setting the ground rules for the medical x-ray technology is found in good practice. If the Oak Ridge National Laboratory can give a chest x ray with an average skin dose of approximately 15 mrem, why does the average skin dose in the United States reach 504 mrem, or 34 times that of Oak Ridge National Laboratory? The "Nationwide Evaluation of X-Ray Trends" is demonstrating that a safer range of exposure can be achieved in different examinations.

Finally, physicians and dentists themselves have questioned the performance of their colleagues. John McClenahan's remarks before this group last year is an example; others have cautioned the medical community periodically. It is instructive to read the cautionary statements over the years and notice the similarity of advice. On one occasion about 15 years ago, Russell Morgan, a leading radiologist, stated in Congressional testimony that, "The freedom [for physicians and dentists] to determine that x rays are needed in a particular situation does not carry with it the right to use x-ray equipment improperly." He concluded that "There must be regulation of x-ray equipment in its technical use and there must be provision for determining whether or not physicians are employing their equipment safely. If such equipment is being used improperly, mechanisms should be available to put it right." Morgan, from time to time, reiterated this viewpoint.

Tensions exist between radiologists and other physicians. Radiologists are aware that their medical associates frequently do not adhere to their performance standards. But, they are reluctant, somehow, to criticize them publicly. The support given to licensure of technicians by radiologists in Massachusetts, recently, represents an example of responsible self-regulation, which is welcome from a consumer viewpoint. Despite these efforts, members of the medical profession continue to resist candid criticism from their colleagues and remain more concerned about the risk to their professional creditability that change seems to imply for them than about the risk to people from unnecessary radiation exposure--labelling it as theoretical and not a real hazard.

Nonetheless, despite these small initiatives and the limits on medical discretion, there does not exist a visible, formal public commitment to the reduction of unnecessary exposure by the medical community. Such a commitment, in my view, would include admitting candidly the existence of a problem, recognizing physicians and dentists as part of the problem and also as part of its solution; attacking programmatically and aggressively excessive uses of x ray that result from the threat of malpractice suits, availability of medical insurance, ill considered patient requests, and injudicious medical usage. We need to focus our inquiries directly on the medical profession. Such a focus is necessary because the medical profession plays a significant part in problem making that needs to be understood before it can play a significant part in problem solving. The medical profession carries a heavy responsibility for correcting bad x-ray practices.

Business as usual also characterizes health physicists except for a special few who deplore their collective performance regarding x rays. Some health physicists have allowed the medical profession to silence them with the assertion that an M.D. is required before one can legitimately participate in the benefit/risk analysis regarding patients.

Equipment manufacturers do not appear to set their priorities with the 1968 Act in mind. From that point on until the time that the Government published the first standard, manufacturers knew that they would have to adhere to standards. Yet when the standard was put out for comment and a deadline was set, manufacturers asked for an extension. A consumer wonders why?

The leadership of radiologic technologists attempts to improve performance standards against substantial odds. Government regulators who work with all these interests of differing power and influence must somehow remain independent enough to fulfill the intent and mission of the 1968 law. Their position is made more difficult because the victims or potential victims of misuses of x rays are not organized to make their voices systematically heard.

From the crossfire of these special interests, those at risk from unnecessary exposure and unnecessary x rays lose more than they gain. Virtually forgotten patients and their progeny, operators of x-ray equipment, unsuspecting victims such as receptionists and neighbors of x-ray equipment. All these people do not seem to be the focal points of active concern in the interplay of special interests regardless of assertions to the contrary. It is useful to ask at this point why the exposure is more than that required for reliable diagnostic information and therefore unnecessary. Can we really say that unnecessary risk is worth the benefit? From the patient's point of view, is the cost to health justifiable? Are risk/benefit assessments relevant when we are talking about unnecessary exposure or unnecessary use of x rays?

How the special interests in the diagnostic radiology problem crossfire carries certain consequences for radiation control programs. One consequence is the task of building a strong patient/consumer force for safer uses of x rays is downgraded, if not ignored, completely. The active development of a public interest in the management of diagnostic x rays is a political act and would affect the position of the different interests, helping some and hindering others. For the medical interests who favor a voluntary system of controlled accountability, it would be a threatening act. The Government agency that tries to organize patient/consumer risks is losing the favor of those who presently have power and status in the medical x-ray community and with whom Government agencies have often worked closely.

Crossfire of interests also leaves unresolved the issue of licensing operators of x-ray equipment. In this area, the American Society for Radiologic Technologists favors Federal licensure to assure common standards for consistent and competent performance. But, their advocacy is often thwarted by the view of Federal officals in the Department of Health, Education, and Welfare opposing Federal licensure; also the medical lobby that would lose control over part of the system if standards for operators are established independent of it. By the same token, standards would give status and some influence to radiologic technicians. But, they face an uphill journey. Their position is a difficult one—having to contend with older, powerfully entrenched groups, the costs of licensure for physicians and unlicensed technologists, and similar questions. Setting minimum requirements to assure citizens a basic standard of quality wherever they find themselves when illness occurs remains unsettled. I am aware that licensure can be abused; but, as in other fields, we can build in safeguards and mechanisms to identify and correct abuses as the benefits of licensure are developed.

The New York State experience is instructive. It is reported that its licensing program has apparently produced technologists who are committed to careers in this area and whose interest in patient care and radiation safety is resulting in higher quality in radiographs.

Crossfire of interests appears to be shaping the current effort to develop a pregnancy awareness program. After months of work and discussion, the Bureau of Radiological Health published in the FEDERAL REGISTER last December an Advance Notice of Proposed Recommendation regarding medical radiation exposure to women of childbearing age. It will be months, again, I suspect before the proposed guidelines for general clinical use are presented for public comment. Also troublesome are some of the questions on which comments are sought. In view of what we know about the risks to embryo and fetus if irradiated, why is comment needed on such questions as, "Is it advisable to recommend to institutions that the physician ordering the examination indicate on the referral slip whether or not the patient is or could be pregnant?" Another, "Is it advisable to recommend to institutions that the physician ordering examination indicate on the referral slip whether he would be satisfied with the limited study, that is, modified to the routine manner of performance on a patient known or suspected to be pregnant?" The interests of the patient would clearly be served if such information is recorded. "What is the reason," asks the consumer, "for posing this kind of question in the first place?" Does it relate to the interplay of interests that shapes how diagnostic radiology is managed?

Moreover, delays are incurred in getting information out to women about the hazards of x radiation during pregnancy and in a woman's childbearing years. Some information is out -tell your doctor whether or not you suspect you are pregnant, and that type of information. But, no information that I have seen is yet out on the consequences that have been observed from such irradiation. I suspect information for women is probably the least developed aspect of the pregnancy-awareness program and the aspect about which there is the greatest lack of unanimity in the Bureau of Radiological Health. Significant problems involve when and how to begin informing women of potential hazards of x rays during pregnancy. Some Government officials think that while it is their duty to inform, it is also their duty not to cause a panic; so they move slowly.

Question: Who will be more panicked -women who learn of the risks and may hold their physicians responsible and accountable in this regard, or a physician who will increasingly have to respond to knowledgeable patients, with practical consequences for the patient/physician relationship? Sometimes I wonder if Government regulators can really appreciate the disbelief some of us have upon learning, for example, that physicians still have to learn or be persuaded about the significance of x rays to embryos and fetuses. It is also surprising that the pilot program that the Bureau of Radiological Health is conducting to make physicians more aware--at least one of the pilot programs--is being held at Massachusetts General Hospital where one would think physicians would now know the significance of x rays to embryos and fetuses.

In closing, diagnostic radiology provides us with one of many examples where the technology has outstripped our biology. It renders people really vulnerable; it is a vulnerability that they could not avoid. If the body has no way of reacting, no way to avoid the danger, it is a silent violence whose consequences come years later, and a cause/effect relationship is difficult to establish. At the same time that technology has outstripped our biology, it has outstripped our institutions. Readjustments are imperative. Since radiation control program directors are on the firing line where things happen, you have a unique opportunity to define these readjustments and advocate their implementation in order to get your job done.

Earlier I discussed opportunities for improving performance, labeling them as limits on medical discretion. But you can create many more opportunities with the aim of developing a new ethic of responsibility equal to the kinds of harmful consequences that will come if we do not in fact manage diagnostic radiation in the people's interest. I would urge you to get more involved with people whose lives are being affected. If that means seeing people who have been irradiated, then try and do that. Recently, I saw in a museum how mice acted under the impact of radiation and the sight was sobering. Experts involved in managing important public health programs should seek such exposure, should put themselves in jeopardy; it is a very great discipline on one's performance.

Specifically as to how you might participate in setting the requirements of the readjustments that will be required, I would like to make a couple of modest suggestions in closing. Why not consider calling a conference of physicians and dentists, getting a commitment from them to cooperate with you in checking their x-ray equipment and in educating the public on what the technical possibilities are. Oftentimes, if you can arrange to get a group like that on your side, understanding your problems, understanding the benefit to them if they correct these abuses, much can be accomplished. If you take the public as your natural ally, even more can be done.

I would also suggest calling a conference of interested citizens. There are many, many resources out there that could make your jobs much easier, if you build alliances with your natural allies, as I am calling them. The public interest research groups around the country, made up of activated students, and others, and community-based groups are a rich resource. Community colleges also provide links with the community that could make your job easier.

Finally, I would urge more communication among yourselves, aside from this annual meeting. There is nothing like getting together to air your professional complaints and to try and set the requirements of your work, without anybody else listening in, with no holds barred. I am reminded of the observation made by somebody that if one person complains, he or she is odd; if two people complain, they are suspect; if fifty complain, they have a movement. Good luck.

RISK-BENEFIT DECISIONS - A PHYSICIAN'S RESPONSIBILITY

Dr. Robert E. Wise
Chief Executive Officer and Chairman of the Board of Governors
Lahey Clinic Foundation

There is every reason to hope that some good can come out of this for all of us. For me, your kind invitation and indulgence may enhance my standing in Boston to the point where my friend Gerry Parker might return my phone calls and stop growling at me. For you, I hope I can leave a feeling that many of my colleagues in radiology welcome your responsibility and your professionalism in areas which obviously concern all of us.

For more than 60 years now, radiologists have been concerned about radiation safety. For some of my early predecessors, it was an immediate problem. They had to learn the characteristics of the invisible ray the hard way -- on themselves and sometimes on their patients. And so they did, and we have all been the beneficiaries of their bitterly won knowledge about ionizing radiation. As a result, we have the opportunity and the leisure to wrestle with philosophical concepts about linear or quadratic hypotheses. We can and do rely upon a strong framework of professional and public health standards for medical uses of ionizing radiation.

On the business of radiation safety, I would contend that in more than 60 years, radiologists have not grown weary of well doing. It continues to be a matter of our professional concern and activity. Dr. Reynold Brown, who will also speak to you, has devoted much of his career to carrying on battles for rational approaches to radiation safety reports. He does not grow weary of well doing and he knows a lot more about the subject in perspective than I do.

I mention this historical perspective lest there be some who believe or suggest that radiologists are indifferent to the nature of ionizing radiation. For most of the history of manmade ionizing radiation, our professional concerns and those of our physicist colleagues were all the concerns there were. In 1928, radiologists persuaded the Federal Government to assign one man at the National Bureau of Standards to work with ionizing radiation. Out of that impetus and 48 years of support came the current National Council for Radiation Protection and Measurement. A few years later, radiologists were very much involved in the dawn of the atomic age. Still later, the American College of Radiology lobbied successfully for the creation of what is now the Bureau of Radiological Health. Shortly after that, members of the College worked with the Council of State Governments to draft the model statutes from which most of your programs have grown.

All of this proves that we used to be nice fellows. But what have we done about the problem lately? Why hasn't it been solved or chased away? I plan to leave the details of our current programs to Reynold Brown who has planned and executed most of them. Instead, I would address a philosophy of radiation uses which to us in radiology is the crux of the whole issue. In taking this tack, I do not suggest that all is either well or unwell. I would not deny you the horror stories we might share. Radiologists do not undertake all medical radiation exposures. They do not invariably do those in their hands impeccably. There is a need for your involvement and your sanctions in the encouragement and/or enforcement of good practice.

But I would start with a truism. Good radiology is safe radiology. Safe radiology is good radiology. By this I mean that the right amount of radiation to be used is the exact amount needed to produce a valid image. Over- or underexposure detracts from the image. Any radiation used in a nondiagnostic examination is wasted.

It has been said with malicious intent that medical exposures are by far the largest source of manmade ionizing radiation to which the human race is subject. This is a reflection of a well-ordered society wherein we use ionizing radiation safely for a wide variety of purposes. Among them are the medical examinations and treatments which constitute the practice of radiology. If we can use this radiation in a fashion which allows its acknowledged benefits to outweigh its real or theoretical risks, then all is not lost. I would suggest that such is essentially our situation.

It is not a situation which arises out of happenstance. It is one which must be lodged in the minds of the medical profession and inculcated with unending effort. It must be one of the many factors in the mind of a physician assuming the care of a patient. Those of you in the public section can and do contribute significantly to the safety of equipment, its maintenance in good order, the credentialing of radiation users, and occasionally the punishment of the aberrant.

But the crux lies in physician judgment. The first judgment factor is the choice by a patient's physician of an examination with x rays or isotopes to determine the true state of the patient's interior. Whatever the radiation risk, this is less traumatic than cutting him open to peer inside.

But once the need has been established in the mind of a responsible physician the equation reverts to my truism. Good radiology is safe radiology and safe radiology is good radiology. The choice of procedures, their extent, the technique to be used, the followup are all directed to producing information to make a diagnosis. If the examination contributes to the diagnosis with a reasonable usage of radiation, then the truism holds. If it fails its purpose, then the truism is reversed. It was bad practice, unsafe practice. The information was not useful. The radiation was wasted.

A year ago, my urbane colleague, John McClenahan spoke to you about the reverse side of my truism. He shared with you some of the concerns which doctors have about their own calling and about many of their own colleagues. I'm sure you were entertained, stimulated, and perhaps perplexed by his reservations. However, Dr. McClenahan did not suggest that the problems he elucidated would be well solved by removing the physician's judgment. Rather, I think he suggested that most physicians need some help in using better judgment about radiologic examinations.

Providing such help is a proper role for radiologic organizations and in some contexts for public officials, as well. Again, I would suggest that we are not doing badly together, even if both sides have much opportunity for improvement.

A physician begins with a clinical decision. He looks at his patient and says, "I think we better get some x rays." About two-thirds of the time, if we can trust the Bureau of Radiological Health, that doctor trundles the patient off to a radiologist. Along with the patient comes some sort of referral slip. On the basis of that referral, we do our thing and communicate the results, or at least our opinion back to the referring doctor. He takes our conclusion, integrates it with any other data and reaches a diagnosis. This leads to treatment, or, in dire cases, to the avoidance of treatment.

Our basic question starts with the clinician's decision. What information did he need? Could it have been obtained by other means as quickly and reliably? Did the examination requested have any possibility of relating to his clinical suspicions? What contribution can the x-ray finding make to the clinician's management of the patient? This is a concept we have called radiologic efficacy.

For nearly 5 years, the College has been engaged in developing a methodology to measure the efficacy of radiologic examinations. It has not been easy or simple. Our clinical colleagues say that some of our examinations are tremendously efficacious in warding off or defending against poorly founded malpractice actions.

But basically we are seeking a way of determining the impact of the x-ray examination on the physician's management of his patient. If it helps, it is efficacious. If it does not, it is nonefficacious. A simple example might help. A patient with a painful, swollen ankle may have a sprain or a fracture. It is the x-ray view which tells the story. If it confirms fracture, the treatment is obvious. If it rules out fracture, it is equally efficacious. In either case it has been the basis of clinical management of the patient's problem.

Most examples are not so clear-cut. But you get the idea. Our choice of the proper patient to receive the proper examination must be valid if your contributions to good equipment and good practice are to count for anything.

Radiologists have been taxed and often properly so for their reluctance to challenge their referring physicians. We do routine studies without questioning either the referral or the patient himself. For film studies, we never see the patient. We could argue that we must rely upon the clinician for his decision to seek an x-ray finding just as he relies upon us to discover and identify the patient's problem.

But as John McClenahan detailed, some of our colleagues refer casually and carelessly. Where we find such patterns emerging, I think we have a responsibility to correct them. Indeed, in the newly founded professional standards review organizations, we will have a legal obligation to make such judgments.

When we come to the selection of technique, the selection and monitoring of equipment, the training and credentialing of our helpers, we recognize and appreciate your help in the public sector.

We are working for the same thing — good radiology which is safe radiology.

Then we come to the final portion of the process. Bill Klem, the famous umpire, once told an indignent Leo Durocher, "You're not out, you're not safe, you're not nothing till I call you something." Essentially that's true about the x-ray images which have been created of somebody's patient.

If we cannot see it, we cannot call it. Elsewhere on your program is a presentation of a project in West Virginia in which the State radiation personnel attempted to assess and help to correct shortcomings in radiography. We knew that these shortcomings were plentiful in West Virginia and perhaps 49 other States. Our experience in the black lung programs documented it for West Virginia. I'm happy to note that the College and its West Virginia chapter cooperated with Beattie De Bord and the Bureau of Radiological Health in the design of the project.

With help from the Bureau of Radiological Health, a task force from the College is looking at a series of problems bearing upon radiographic quality. The results of these efforts will be available to all of you, as well as to all radiologists and to the manufacturers of x-ray equipment and supplies.

What has all this to do with radiation safety? Again, my truism. Good, productive efficacious radiology is safe radiology. Only that which is needed is used.

I would speak to one other point of some concern. This is the question of quotas and records for medical radiation exposures. From time to time, proposals that all of us should keep a radiation diary are revived, as though such records would be reliable or useful. We must suggest that they would be neither. In addition, they would represent a ponderous accumulation of misleading information more likely to hinder than to help the medical care of a patient.

This does not mean that we are insensititive or uncaring about the amount of radiation received by patients. Rather, it means that we choose to cling to clinical needs as the paramount basis for making medical x-ray exposures. Certainly we should obtain and review existing films. Certainly we should amend obsolete protocols to eliminate admission chests and other unproductive examinations.

But if a patient presents a swollen and painful ankle resulting from an accident today, a film of that ankle taken last week is not helpful. A chest taken 6 months earlier might demonstrate the absence of pneumonia or a coin lesion 6 months ago. But the patient is presenting a problem here and now. So here and now is where and when we need to know the condition of his lung fields. It is a clinical problem, requiring a clinical solution. You can help us in many ways. But as doctors, we have to make and live with decisions to make these examinations and to rely upon their results.

I have talked about the role of the radiologist in a clinical setting at a time when many patterns are changing. Over the past decade, the numbers of trained and certified radiologists have nearly tripled in this country. According to an extensive study by the American College of Radiology, we are close to reaching an equilibrium of demand and supply of radiology services by radiologists. To say it another way, we are nearly in a position to suggest that most radiological examinations can be performed by radiologists. In all modesty, we think that this would be beneficial to the public, particularly as regards radiation safety.

We have not sought the exclusive use of ionizing radiation by radiologists through legislative or regulatory mechanisms, nor do we intend to. This is too restrictive. There will always be communities too small and too remote to receive regular attention from a radiologist. There are some procedures which other physicians with limited x-ray training can perform and interpret adequately. There are sophisticated procedures, such as coronary arteriography, that were brought to radiology from other disciplines. If we, as radiologists, can do it better and safer, if we are available, then we don't need sanctions to assert a monopoly. If we can't produce, then we should not try to hide behind laws or regulations.

It may be of interest to note that the strongest pressures to limit radiology to radiologists come from outside of medicine. They are mostly economic. It demonstrably costs less for third party health carriers where radiologists do the radiology. The attending physician tends to require fewer examinations than if he has his own x-ray machine. In some States, the charge for x-ray examinations by radiologists is lower than the charge for the same examination by other physicians. I do not urge that you join in this unless you have an overwhelming attraction for family fights. But I would wish you to be aware of the tendency and the reasons for it.

Another push in the same direction is the assertion of domain over procurement of sophisticated x-ray equipment by local health planning agencies. As these agencies spread across the land, there will be further centralization of x-ray facilities -- in those institutions with demonstrable need and under the control of competent and qualified physicians, physicists, and other scientists. You can and should play a role with these planning agencies. They need all the expertise you and we can provide them.

Back in 1959, the American College of Radiology assisted in preparing model laws for State radiation control programs because its leaders recognized a public stake in good radiation practice. Our presence here represents a continued recognition of that stake. Recognizing such a public stake does not represent any diminution of our historic interest and concerns about radiation uses. Thus, we have not passed these burdens on to you with a shrug.

The problems have not gone away, even with our combined efforts. There is plenty to be done for all. You can do some things which we cannot do within the ranks of medicine. We can accomplish some things you cannot achieve by regulations and inspection. We are all headed in the same direction. Remember, good radiology is safe radiology.

WHAT ARE OUR OPTIONS?

Reynold F. Brown
Director, Radiological Health Sciences Education Project
University of California Medical Center
San Francisco, California

My assignment was to try to find what was most significant in the remarks of the preceding speaker. The thing that impressed me, personally, the most and I hope it impressed you is that I heard some things today that we probably would not have heard a decade ago. As a matter of fact, it occurred to me that Dr. Nader had to go back 10 years to find a testimony with which she disagreed. I think things have changed in this country. I think that is an important observation.

I think the response and the kind of talk you heard from Dr. Wise today is quite a bit different from the testimony that went into the Congressional Record a decade ago. I think that participation on the part of radiology is changing--you are changing, we are changing, consumers are changing, the world keeps changing, we are doing better. If you have hit the mule with the two-by-four, I think you have his attention. I think you are now getting a kind of cooperation from medicine that you were talking about 10 years ago.

If I resent anything, it is the implication or the attempt to portray all of this in an adversary position. I know that is the foundation of American due process; but all of us have a right of free expression, without the implication that we are somehow adversaries. We can progress together towards common goals without the creation of that kind of antagonism.

If I were mischievous, however, I do not understand why Oak Ridge is using twice the exposure that is necessary for good chest exams. If I can get on to the matter at hand and come back to the general title before I go into "What Are the Options," let's look at this slide of the risk/benefit equation.

We have struggled with the benefit/risk equation and the admonition that was given to medicine more than 10 years ago--that the way to practice good radiology is to weigh the benefit versus the risk. In radiology, you have to weigh the benefit before you do the procedure; you cannot do it afterwards. It is not like deciding to do the appendectomy after you have made a diagnosis of appendicitis. It is a very peculiar equation.

This is a table from Dr. Priscilla Laws' Consumer Guide. I have taken her figures and the reason I have used them is I did not want you to think that I sandbagged you with some self-constructed figures. The second column is the estimated annual excess deaths per hundred thousand exams. It varies from 3 to 10 in G.I. series, and it goes down to radiographic chests at .1, and everything in between. Whether or not these figures are valid, they are acceptable for purposes of education and trying to gain a perspective.

The last column is the cancer death incidence per hundred thousand from the National Cancer Society figures.In every case you will find that the cancer incidence in unselected age groups--this would of course be variable and proportional to age--is in nearly every case or in every case a positive number. It is greater than the induced risk from doing x-ray examinations. Therefore, in any group of people in which you eliminate some patients because of pregnancy or whatever, there is a price in information that we pay. We are going to lose at least this minimal amount of case finding, because this is pure serendipity. This would be the incidence on entirely asymptomatic patients. The dilemma is not an easy one, and it is not going to lend itself to some very simplistic kind of consideration. You are not going to change the rules of examination to influence patient benefit without paying a price in lost information. These are the kinds of things we are trying to wrestle with in terms of benefit versus risk. We have almost given up on trying to use this. I think what we want done is a very careful selection of the patient on the basis of productivity versus the utilization factor.

Those of you who have heard me talk about this before, have heard me talk about the system in radiology that starts with the selector being a physician/patient relationship and the fact that we should have a program in this area of equal importance to every other program. The middle group is the conductor and the equipment; we should have a program there. Then at the last we have the interpreter; maybe this is the most important one in the entire chain. He forms the feedback that produces the modification of the selector and the patient. This process is continually changing because medicine is continually changing. Medicine is undergoing something that is almost a revolution in terms of the CAT scanners that you are going to hear about later. We have to wrestle with these things as they come; we cannot turn our back on them. We have to meet and resolve them. But, there is a system; the system is in place. You are a part of that system, and we are a part of that system. The consumers are part of that system; the radiobiologists are part of that system. Your effectiveness has been tremendous.

As a matter of fact, let me lay a burden upon you. You have been so effective that the kinds of articles that appear in the LADIES HOME JOURNAL, titled, "My Awful Decision," was probably a true story. It involved a lady, who had a low back x-ray examination, and was inadvertently found to be pregnant and had a subsequent abortion with great anguish. Now, let me put part of that responsibility on you as you have put it on me for putting people at risk in the first place. This was a real live death. It is the result of the system. The system is working. How well is it working? It is working, as near as we can tell, so that there may be a thousand of these deaths in the United States each year. Those are documented deaths; they are not hypotheses; they are not no-threshold phenomena; they are the level of our effectiveness. People are listening. Is this where you want it to be? Have you tweaked the system and this is the way you want it done? Would you rather not have the woman examined with her low back, and take the loss of information--do without x rays during this particular time period? Medicine will be responsive to what society decrees. In the last analysis the public will be heard, and medicine will be practiced as society decrees.

But, it is not an easy system, and we have all gained a new responsibility. Maybe we have gone too far; maybe that is not what we had in mind. It is an interesting observation about these thousand abortions that have been done on women who were inadvertently examined; we can find practically none--we should have been able to find them--that were performed on women who were known to be pregnant when they had their x-ray examinations--in other words, a deliberate examination in the face of known pregnancy.

Yet the risk must be the same, if we were to be truly rational. We probably should be aborting all the pregnant people on the basis of the risk. Most of these babies are normal. Under the worst assumptions, the risk to these one thousand babies could not have been more than one or two. I use as my authority for that figure the Russells from Oak Ridge. Yet the other 995 or 998 were wanted babies. These are wanted children that have been lost due to our system and the way we are presently operating.

All of us are going to have to work harder. We are going to have to work with the system. The system is working; you have accountability. I can lay these autopsy reports on the table, for instance. You are effective; we are effective. There has been a change in attitude on the part of radiologists. You heard it today; you have been hearing it for 10 years.

The American College of Radiology program for gonadal shielding is another thing that illustrates the change in radiology. What we have said is that we were tired of writing new documents. We wrote one for the International Committee on Radiation Protection called "Protection of the Patient." The NCRP has written documents. Dr. Nader referred to the "Guide to Good Practice." We decided that we were not going to go anywhere with writing more documents, that we were going to go into things called action programs. We were not going to only say that gonadal shielding is desirable. We were going to go out, try to find out how to make people change their habits and their practices, and get on with doing the things that we were committed to. We are still into that. As a matter of fact, we have maintained that competent individuals, working with adequate equipment, is a far better way to go than trying to develop idiot machines that do automatic things for competent people at a lesser level of quality. The thing we would like to look into here today as a constructive idea is an emphasis on professionalism and performance to the level of your competency. That has to do with the attending physician; it has to do with the consumer; it has to do with the conductor; and it has to do with the interpreter. What we want to nourish in this country is a concept of professionalism in every area with a high level of performance--that is where we want to go. We are not going to solve these problems immediately--you and I are going to have jobs for a long time in the future. Things are not getting any easier; they are, in fact, going to get harder as we go on. One thing is going to be sure--radiation exposure and dose is going to continue to go down. It is going to go down dramatically. You are an effective system; you are part of an effective system. Doctors have changed their attitudes; they want to be part of this system in getting radiology where society wants it to be. That is the commitment. Those are the options. Radiologists want to work with regulators; I am sure regulators want to work with consumers and radiologists. With this kind of constructive approach we are going to go farther and faster than we could ever go by any kind of adversary relationship.

DISCUSSSION

MR. JOHNSON: Dr. Nader, I would like to question the number that you gave for the chest exposure. You said that you can get a chest exposure for 15 millirem at Oak Ridge National Laboratory and you gave a number of 504 millirem on a national average.

DR. NADER: For the 504 number, I drew on Congressional testimony that Karl Morgan gave in the late 1960's.

MR. JOHNSON: In the next room at the table clinic there is data that shows nationwide averages for a chest now are about 25 millirems or even below per chest per exposure. That is the NEXT data, coming from about 30 States.

MR. TAYLOR: Dr. Nader referred, unfortunately, to reasons why the press coverage seemed to have died off in the last decade or so since the 1967-68 hearings. I wonder if she would like to comment on what might be a more valid reason, or two reasons: (1) that some of the seemingly most important testimony given by a non-governmental witness at those hearings has been since found to be, for the most part, fallacious and incorrect; and (2) some testimony that was introduced by the BRH, which was an honest mistake, in that they had not completed the analysis of their very significant dose data at that time, that turned out during the last several years to be 1/3 or perhaps 1/4 of what it was thought to be in 1967 (comparably down with the best radiology done in other parts of the world as far as we are aware of it). Since only a small fraction of that radiation is regarded as unnecessary, this means (and the public is; now becoming aware of this) that the unnecessary radiations you are talking about in those exposure series were equivalent to the difference in radiations you get from working in downtown Washington and going to the countryside in Maryland, let us say, at an altitude of 450 feet in the evenings. Those are the levels you are talking about.

DR. NADER: You referred to press coverage. I was not talking about why the press was not covering the topic anymore. I was talking about the reasons that the momentum for reducing unnecessary exposure did not remain at the level that it was in 1967-68; one was press coverage. Usually if the press follows the development of a line of work, it is instructive that the people involved in that line of work stay on their toes a little more. This is true of all of us. I am not just singling out physicians or any other group. I was trying to indicate that visibility is a great discipliner, and program directors should consciously build in visibility because it can help them stay conscious about what they are doing.

By the way, Dr. Brown, the ORNL performance can be improved, but in order to lower the exposure even more, they would have to get different machines. I gave the ORNL exposure to indicate a standard that has been achieved. If an x-ray can be given with still lower exposure, that is all to the good. My point is that we at least follow the best practice to date, trying at the same time to improve performance whenever possible.

Regarding unnecessary exposure, Dr. Taylor, I think we are talking about a larger problem than you have just described. The problem of unnecessary exposure from diagnostic radiology is of sufficient magnitude to assure, as Dr. Brown indicated, there will be jobs for quite a long time in this area of concern.

Could I respond to Dr. Wise's comment on control and the issue of voluntary versus mandatory controls. No problem that is as pervasive as the medical x-ray problem, and as important, can be mandated out of existence. Its resolution is going to depend on a lot of good will, a lot of education on the part of the principals, and understanding and willingness to change their ways. However, there are some controls that can be set and can help in the corrective process. Illinois is trying to move in this direction by setting performance standards for certain diagnostic examinations. Would you agree that that kind of standard is appropriate?

DR. WISE: It is most unfortunate that while I stand in the land of Lincoln, I am not familiar with all the details of that program. However, I suspect that it may be a reflection of what is taking place in modern society today. Some of the performance standards that are being, and I use this word properly, "foisted" upon us in our PSRO areas--where overintellect at strained positions tells us that we know precisely to go about conducting an examination, a series of examinations, and so forth. So, if this is what it was all about; then I would reject, in all probability without knowing the details, these performance standards. I may be completely wrong; I really do not know them, and I apologize that I do not. On the other hand, I am unable to read everything that has been printed in this country.

DR. BROWN: I do know a little bit about Illinois, and so do you; so I am not going to go into the details. But I just want to give that as an illustration of the kind of nonpartisanship--I will not use the word "cooperation" because I think it is an advantage to stay at arms length, and that the radiologists in Illinois played a part, as those of you in the State know, in the development of the standards. At this point in time, I am not going to advocate that we go national with the standards. I think they were a very healthy R&D. Let us see what happens to them. Dr. Nader says they can improve dose rates at Oak Ridge by going to a new machine, and after they buy that one, 6 months from then there will be a another one at 3-1/2. How often are you going to scrap them? This was the kind of adverse comment that we got, or at least the comment that was anti these sort of speed limits in radiation exposure. Let me say that in general those of us who sit in councils that are trying to speak for radiology applaud Illinois. We are delighted that Illinois is in a research posture, because we are going to the same place. As Dr. Wise said, the commitment, the present-day thing is that we are as committed as anybody--that safe radiology is good radiology. The only thing that I want to be sure that we keep up on the board and up on all our walls and that all of us do in radiation control as the number one, two, and three goal is to make the diagnosis. Let us be careful that we never sacrifice that. Within that parameter, let us get on with the task. If Illinois has found us a better way, let us all do it. Let us watch it carefully and make sure that it is well designed to get us the information.

DR. BENSON: Dr. Nader asked a series of questions on our x rays in pregnancy program--the AMPR. One of her questions was, why do we go so slowly? I guess I share concern there, I wish we would be going faster with that program. I think Dr. Brown answered the question in part when he spoke of the thousand abortions. I think that if we came out with strong recommendations, or recommendations immediately, without some kind of due process, we may in fact be pushing that number higher--that also is of concern to me. I think even if we had specific answers to how to improve the situation, relevant to those women who might be pregnant that are being x-rayed; we just have to recognize that we cannot snap our fingers and have those recommendations implemented across the country. Again, due process has to occur. I think as a social scientist, no one here better than Dr. Nader would understand that.

Lastly, I would point out that the MTA study is not only a pilot; but it is also a study to get specific data so that we can go to other facilities and say, "As a result of this awareness program and as a result of the request for exam modifications, here are specific results. We suggest that you and other facilities also use those."

MS. WATKINS: I would like to ask Dr. Wise, in those instances where hospitals still use preadmission x rays before admitting patients, is this a wise procedure and if not, how should regulatory programs go about working with the hospitals to stop this practice?

DR. WISE: I do not think you were playing with words when you asked if it was a wise procedure. I would say it is an unwise procedure. We agree generally, as radiologists, that highly structured programs which mandate examinations on some sort of a routine basis really are not valid today. There must be a specific and good reason for this.

Now, I think, if I could digress for just a moment, there is an article which appeared recently, within the last 2 weeks, in the New England Journal of Medicine entitled, "Cat Fever." In that one example given as to how medicine, in general, had learned its lessons was the fact that we no longer use survey radiology for chest examinations in the detection of tuberculosis. Well, I think that is true; but I think with that type of syllogism or that type of a basic premise we could probably prove anything. The facts of the matter, of course, are we cleaned up tuberculosis to a large degree in this country between x rays and drugs; and we just simply no longer have to use them. But in general response to your question, the answer is, as far as I am concerned, no we should not be doing these.

Some parties have taken issue with this. One of the means of control, in fact, to get to the second part of your question has been that Blue Shield, for instance, has refused to recognize payment and to make payment on an independent billing basis for chest x rays that are mandated by the governing body of the hospital. This is one method that can be used, and there are others.

DR. PARAS: Some time ago, my son who is 16 years old wanted to take a part-time job for about $3.00 a week, but he had to take an x ray before he started working. No x rays, no work. I tell you that good radiology, safe radiology, can use what is needed. I am asking the question, is this type of procedure needed with today's knowledge?

DR. WISE: I think the answer to that is very much the same as to the previous question. We are evolving our staff; we are evolving our concepts; and we are evolving our philosophies. I think that if any of us go back with any of our particular fields and cover 25 or 30 years, we had certain standards and philosophies wherein the evolution of the last 25 or 30 years suddenly have no validity in modern society. We can get to the concept that if it is unnecessary and there is not a specific reason for it, then as far as I am concerned, I think in the minds of most that these are not valid requirements.

Now on the other hand, let us take food handlers. Can it be valid there? I think it can be. I think it is in the public interest to require chest x rays, for instance, if one is going to go into public food handling. I think this is important. But, if the man is going to a machine shop, no--except to prove the fact that he does not have preexisting silicosis. I am saying that these concepts are evolving and, unless there is a specific reason for it, we in radiology do not believe that an examination should be required as a principle.

DR. NADER: I would like to respond Dr. Brown's point about adversary relationships. For a long, long time the experts talked about diagnostic radiology and the problems of unnecessary exposure. When the debate became public in 1967-68, it was not that the questions were new; it was that there were new people involved who had not before participated. When newcomers begin talking about the problems, experts in the subject area say, "Well, what else is new? What is all the flap about?" It is happening now with nuclear power plants.

What is new is the public participation, and the way the public came to participate, Dr. Brown, is to have had some outsiders come up and say, "We are questioning the way the business has been conducted over these years." You are bound to have some adversarial relationships and situations arise. Out of that friction comes a public record that is quite useful for citizens to become informed about the problem.

In 1959 there were some hearings held in the Congress on the subject of diagnostic radiology. The only people who testified were mainly the physicians; I could hardly find any data in that hearing record. This was not true in 1967-68, when different kinds of people who were concerned about the problem testified. I think I alluded in my comments to the change in attitudes on the part of some radiologists and even some physicians. When one talks about a whole community, that does not mean everybody in that community resists corrective revisions. Fortunately, a few have paved the way. The cautionary statements and their willingness to examine the problem in broadly public forums represent a noteworthy contribution to its solution.

COMPUTERIZED AXIAL TOMOGRAPHIC SCANNERS-- USE, POTENTIAL, AND CONTROL

Gerald M. McDonnel, M.D.
Chairman, Committee on Computed Tomography and
Energent Imaging Modalities
American College of Radiology

It is an honor and a privilege to be one of the College of Radiology representatives to support the Council in this national conference. The title that was given to me is "Computerized Axial Tomography." Like everything else it has gone through some changes. CAT stands for Computerized Axial Tomography. First off, we do not do axial tomography all the time. We do coronal and sagittal scans; and computerized has been changed to computed tomography.

In normal radiography we deal with four densities of material: calcium or bone, air, fat, and water. In tomography we move the tube and the film. It blurs those structures outside the plane of interest. Blurring has the problem of resolution. Godfrey N. Houndsfield, whose name ranks with the name Roentgen now, is a senior research scientist in the Central Research Lab of EMI, Electro-Music, Incorporated, England. In 1969 he began his research with the concept that a computer would allow recovery of large amounts of information lost by the superimposed data in tomography. In 1972 a head scanner was announced with which a multitude of angles with data absorption values were calculated by the computer. It is interesting that the basic scientific papers are written by Kuhl and Oldendorf of this country.

The first head scanning unit was an x-ray tube with two pencil point beams aligned with crystal detectors. The unit is composed of an x-ray generator, controls, the computer with magnetic discs and printer, and the viewing unit, which is a CRT (cathode ray tube). The two beams give two paths of information with each scan of the unit. We can have an 8-millimeter or a 13-millimeter slice of tissue. The gadget moves 1 degree at a time to 180°. Each time it stops, 240 measurements are made and processed by the computer. Therefore, at the end of the scan, or 180°,we have 43,200 measurements of x-ray intensity. The computer creates a picture on a matrix of 160 by 160 pixels. The term "pixels" is a contraction of the words "picture elements." In the first EMI unit, the picture element was 1.5 by 1.5 by 13 millimeters. Now, since I have given you three dimensions, there are those who call a pixel a "boxel."

The first generation head scanners required almost 5 minutes to scan and then several minutes to complete the computer calculation. Upgrading the unit gives us 35 second analysis. The head is placed in a water bag so that the large differences in attenuation of the radiation beam are not encountered. The final image is processed arbitrarily in -500 to +500 units. Minus 500 is air, zero is spinal fluid, and plus 500, the most dense, is bone. These are known as density units, or EMI units. The precision of measurement is 0.5 percent, but it really is actually around 1 percent or 5 EMI units. The actual precision is as low as 3 millimeters, although I think it goes lower than that because very often I can see the septum pellucidum between the anterior horns, and that is no more than a millimeter thick.

In addition to discerning anatomy, spinal fluid, and ventricles, the gadget picks up calcification. I have not seen data to say how much better it is in detecting calcification than conventional x-ray techniques, but I suspect that it is somewhere between a hundred and a thousand times better. The ability to pick up calcification is a strong diagnostic enhancement.

We sometimes give iodinated compounds, such as Remografin or Conray. The contrast material is picked up by increased circulation. We are enhancing approximately 60 percent of all the people that we scan. It is interesting to contemplate that there is an inherent risk with injecting iodinated compounds. We are essentially doubling the number of people at risk to this hazard. The current estimate of death from injecting iodinated compounds is 1 in 40,000. The diagnostic accuracy of the head unit by all those who use it is either 95 or 96 percent. This is accuracy that is unchallenged in most circumstances. The use of the head unit is outstanding in the diagnosis of the cause of hemiparesis. It picks up almost immediately infarct, hemorrhage, or tumor.

I recall being on duty a couple of weeks ago on a Sunday afternnon I was asked for an emergency EMI scan, so we warmed the unit up. The patient was brought by ambulance from his home. It was suspected he had subarachnoid hemorrhage. He came by ambulance to the EMI room; he got his scan; it was subarachnoid hemorrhage. With that he was admitted to the hospital. That is modern medicine.

CT scanning is preeminent in the diagnosis of the size of ventricles in hydrocephalus. In children who have been shunted, it is a remarkable experience to see these little ones come in for an evaluation of the function of the shunt - the illustration of the ventricles. When you finish the examination in less than 5 minutes, you see the smile on their faces, recalling that the diagnosis was made by a pneumoencephalogram, which is often a painful procedure. The unit can be used in following function of the shunt in children and adults. It is useful in adults to demonstrate normal pressure hydrocephalus which is one of the causes of dementia.

The unit will scan orbits. For the first time we can see the retro-orbital structure; such as the optic nerve and the optic muscles. These images are ever so much better than the B scan in looking at the anatomy of the retro-orbital space.

Mr. Will has asked me to give you a comment on the different types of scanners. There are three types of scanners in so-called generation 1, 2, and 3 that we are talking about. I have been talking about generation 1, the EMI head unit. That is the recto-linear pencil beam scanner. The second class is the hybrid scanners, and the third class is the circular pulsed fan beam scanners. In the recto-linear pencil beam scanners, the single beam units are the Neuroscan made by General Electric and the ACTA-Scanner by Pfizer. The multiple pencil beam scanners are the Delta, made by Ohio Nuclear, and EMI. These latter gadgets make two slices per path - the thickness of slice - the slice is the area of diagnostic interest for that particular scan - is 7.5 to 13 millimeters. The scan times, or 180°, is about 5 minutes. The Delta scanner will scan 180° in the head in 2 minutes; 180° in the body in 2 minutes and 40 seconds. The EMI upgraded or updated unit 1010 scans 180° in the head in 60 seconds. The image produced is 160 by 160 pixels (the original EMI gadgets were 80 by 80). The Delta unit scan displays with a 256 by 256 pixel image. Each unit scans at 120 kV at a 15-30 mA, and they all use stationary anode tubes.

Now the hybrid scanners - we are talking about generation 2. The hybrid scanners include the EMI 5005 which is the body scanner, the Philips Tomoscan, and the Syntex System 60. The EMI and the Philips Tomascan use 30 detectors. The Syntex System uses 12 by 15 by unknown (it is a business secret). Picker uses 20 detectors. These gadgets each make one slice per scan. The time for 180° scan is 20 seconds, 27 seconds, or 60 seconds. The Picker unit does 360°, in 20 seconds. Each pass makes from 324,000 to 540,000 density measurements. The image is 320 by 320 (which is double what we are getting in a head unit now), 256 by 256, or 240 by 240. The window levels are a measure of density. Instead of being minus 500 or plus 500, the units go from minus a thousand to plus a thousand. These units all scan at 120 to 160 kV, and 30 to 40 mA. That is generation 2.

Now we come to generation 3, the circular pulsed fan beam scanners. These are multiple cell gas detectors. The detectors are zenon chambers. These include the Neuroscanner by Artronic, Torsoscanner by Artronic, the GE LT/T unit, and the Varian unit. Again each does one slice from 3 to 15 millimeters thick. Scan time for 360° is 5 to 9 seconds. GE announced a scan time of 5 seconds. This is a goal for industry to shoot at. The problem is that GE does not deliver until spring of '77. To give you an idea of the complexity of these circular pulsed fan beam gadgets, the number of detectors go from 128 to 256 to 300 to 320. Remembering some of the problems that we have with two detectors on the basic EMI unit, I can imagine the engineering difficulty with up to 300 and 320 detectors. All of these units utilize a rotating anode with an image matrix display of 256 to 320. They scan at 120 to 130 kV at 100 to 120 mA; their mA is about three times as high as the original units.

We are often asked the question "what is the patient load that these units can handle?" The manufacturer says 8 to 20 a day. But, if you actually are scanning, you find that you are lucky if you get 6 to 8 body unit scans, just because of the logistics involved. In my own installation a normal workday is 12 headscans (this is with the EMI updated), or 16 if we really work hard. Our utilization time is 10 hours a day. That is a little higher than the national average.

How many heads have been scanned? At Mayo Clinic, where they have two head units, they have scanned (as of last week) 15,000. At least one half of all the results are on computer tape. Massachusetts General Hospital has two units, and Dr. Paul New says they have scanned 7,000. My own installation, as of last Friday - has scanned 4,800 heads (patients) since October of 1974, so you see the unit does not sit idle very long. The downtime is negligible although a national survey in January of 1976 said the downtime was 7.3 hours per month. That to me is unacceptable.

As I say the problem of getting people in and out of gadgets is the limiting factor of how many you can do a day. At this point let me say that the procedure is properly done by a radiologist. I can do headscans, but I am not a neuroradiologist. Again it is shown that images are not made by the machines, but by people. You give a poor technologist the best machine available and he can get lousy images, or you can give a good technologist old fashioned machines, and he can make good images.

In January of 1976, of the people responding to a questionnaire - of the 98 units reporting - 81 were EMI's, 8 were ACTA's, 9 were Delta. There are at least 200 head units in place and at least 200 on order. Body units; there are at least 20 in place and at least 100 on order. The R & D for scanners is estimated, and I think realistically so, at one billion dollars per year. The cost of the machine goes from $350,000 to $750,000.

A study out of Toronto on the subject of cost effectiveness says that they have saved - can decrease the cost of medical care by two million dollars per machine per year. The impact on medicine, or neuroradiology; air studies are down about two-thirds in places with head scanners. Angios are down about a third, brain scans are down about a third (brain scans comprise 50 percent of the nuclear medicine procedures), so you see that the scanners have a tremendous impact on nuclear medicine.

The impact on ultrasound is not definite. There has not been enough data base to make conclusions. Take the obverse side of the question: cost effectiveness. They say that even though you do less pneumograms and less angiograms, you must maintain that physical capability to do the study. Therefore, if you do the study, it costs more per examination than it did before; and you may not really be cost effective. I say that it is specious, but that is my personal opinion.

To me there is no doubt that head scanning has had its impact on medicine. To me there is little doubt that body scanning will have an even greater impact. I have mentioned scanners and so on - this quickly leads some to the establishment of a superspecialty. I would decry that. There is no need for a superspecialist in scanning, because scanning cuts across all of medicine and all of radiology. After all, radiology is medical imaging--not just radiology.

Mr. Will has asked me to give a comment on the differences in scanners. I have given you the classes, and I assume he means something about which one should an installation get. It depends on the clinical load. Do you need a head scanner or do you need a body scanner? Do you need a unit that will do heads and bodies? At one installation in Long Island, there is a combination body-head-scanner. They scan heads all day, but they do one body per day. The EMI body scanner scans heads better than the original EMI head scanner - which leads to an aside. You pay $350,000 per head scanner. Then you get a body scanner as we are getting, you have to spend another $90,000 to update your original head scanner so that you can do head scans as good as the body scanner does.

Now, of interest to this group, I presume, is the dosage involved. The dosage for one complete head scan study is 1 to 2.5 rads. This is the value for a single skull film, perhaps. We are talking about a dosage level which is less for a single complete scan than a skull series (at our installation a skull series is seven films). The leak rate from the tube head is 10 mR per hour at 1 meter. They have increased the shielding characteristics in the tube head since those measurements were made. The gonad dose level in air is 10 milliroentgens per hour. With body shielding by the patient's own body - the gonadal dose is 0.1 mR per scan. In the head, you probably use four scans, so that is 0.4 mR. We made measurements in our room at Good Samaritan Hospital in Los Angeles on the scan side of the viewing window, in the plane of rotation of the tube. The scatter radiation is 137 mR per week. On the other side of the window, the control side of the window, again in the axis of rotation of the beam, it is 40 mR per week. I think it is safe. Six feet away in the open doorway between the control room and the scan room, it is 9 mR per week. I think that is safe also.

The dosage in the body unit -- the leak rate is 50 milliroentgens per hour at 1 meter. The dose per scan has not been measured to my knowledge with precise accuracy, but it is about 3 R per scan. We do 4 to 6 slices per patient. If we compare this with conventional tomography of the lung, for instance, which you go front to back through the entire lungs - every scan of the lung is in the order of 10 to 15 rads, depending upon the factors that are used. So, if we go front to back in the lungs, every centimeter (and I have heard no one object to this, because it is the only way to diagnose multiple metastases in lungs) we are talking about 17 or 18 films. If you are talking about 10 rads per film, that is a fair amount of radiation. The dose level for a G.I. series is something under 10 rads to a very limited field.

Now the capabilities of the body scanner are somewhat mind-boggling. These are generation 2 and 3 scanners. Routinely, we can visualize clearly and with accuracy the aorta, the iliac arteries, superior mesenteric artery, renal arteries, pulmonary vessels, and the vena cava. Routinely, we see the spleen, the liver, the gall blader, and bile ducts. Routinely, we see the pancreas, kidney, bladder, seminal vescicles, prostate, and uterus. That is in the normal state.

The pathological state is very simple and straightforward. For example, we see dilated bile ducts. We can detect 1 centimeter of metastases in the liver. This is after the injection of Renografin. We can detect fatty liver without invasive techniques. In the pancreas the technique is pathanomic for carcinoma or cysts. At the Mallinckrodt Institute in St. Louis, of the first 30 cases of carcinoma of the pancreas, 27 were diagnosed accurately by the scanner. Now, that is fantastic. In the kidney - it clearly can differentiate cysts versus carcinoma - and no other technique can do that with the accuracy we are talking about with body scanners.

The biggest problem with the CT scanner, some say, is the cost. Although it is obvious from the utilization rate that I have mentioned to you that they will amortize themselves rather rapidly. To me the biggest problem is to obtain a certificate of need. I am sure there are those of you in the room who will agree to that. State comprehensive health planners have taken the view that if something costs more than $100,000, they must judge its merits. I can see how overbuilding hospital beds would justify that viewpoint. But, I cannot see why it should apply to something that reduces the cost of medical care, if you believe the Toronto study, two million dollars per year, per machine. Each State in each region has a different set of guidelines and criteria. I was charged by the American College of Radiology to devise elements of procurement, or standards of procurement. I have not succeeded, because no matter what I have come up with, there is some part of the country that doesn't agree. For instance, some say that you should have one scanner for every 250,000 people, or 300,000 people. This says one in North Dakota, and you can have five on the west side of Manhattan. It does not make sense. Or let us say you get a scanner because of the number of nuclear scans of the head or angiographic studies of the head that are currently being done. In Kentucky, they say that you cannot have one less than 90 miles from another one. So everybody has their own problems.

A recent survey of all the States shows that only 16 States have fixed guidelines for the procurement of a head scanner. By law, as you all know, to get a head scanner, you must have a certificate of need -- that is if you are a hospital. But, if you are in the private sector or an office, you have no such restriction. All it takes is the money to buy a scanner. But you can foresee that if you have a neurology office or center, (as was published in the Washington Post) and have a CT scanner--a head scanner, self-referral can easily lead to overutilization. Blue Shield and Blue Cross do not like that.

Let us go a little bit further. I think that CT scanning is now part of the practice of medicine. We can practice medicine with an accuracy of 95 percent in the head with considerably less discomfort to the patient than by other techniques. Thus the usual customary and standard practice is the CT scanner. So, it seems to me to be prudent for a hospital to apply for a certificate of need for a CT scanner. If Comprehensive Health Planning refuses, there can not be criticism for not practicing usual and customary medicine.

In the American College of Radiology we maintain that the scanner should be in the Department of Radiology. First off, it is a radiation emitting device. but that is not really the compelling reason. The compelling reason is that the radiologists are accustomed to reconstruction anatomy; cross section anatomy. Even more compelling is the fact that in radiology departments, there are all modalities of diagnostic or medical imaging--nuclear imaging, conventional imaging, and ultrasound. These are not screening gadgets. The body scanner is not a screening gadget. Every examination is tailored, even the head. As I have said the cost of the head unit is $350,000. The body unit is $250,000 to

$750,000, depending on whether you want the Volkswagen or the Cadillac. The cost of examination is somewhere between $150 to $410 per examination: this is for head scans only. A maintenance contract comes with installation of most units for the first year. After that it costs you $25,000 a year to get a maintenance contract. In my own installation we spend $200 a day on Polaroid film. We buy it by the case, which is a little shocking to start with.

There are other uses for scanning both the head and the body - radiation therapy. It is a super gadget for treatment planning because it gives us the true extent of the tumor. A striking example is the determination of the extent of a tumor of the bladder. The ability to scan a bone tumor and search for inguinal or retroperitoneal spread is a major advance.

There is also a CT device for breast scanning. It is an exploratory unit: a prototype. Its advantage is a rapid screening time with a low dose.

In obstetrics, we do not include CT scanners; ultrasound is still the modality to localize the placenta. In ultrasound, which I like to say is tissue characterization, we are having an impact of some sort. I think that the impact of the CT on ultrasound is that the pharmaceutical industry will develop better emitting pharmaceuticals to establish normal tissues, or better identify abnormal tissues.

As for the future, there are going to be more and more scanners. It is my own personal view that every hospital of 100 beds or more will have a scanner. The cost of the scans will be $100, and the cost of a scanner will be of the order of $150,000 - about the price of an x-ray machine.

In summary, I think CT scanners are here to stay.

REPORT ON FEDERAL RADIATION PROTECTION ACTIVITIES - PART I

William J. Dircks
Assistant Executive Director for Operations
U.S. Nuclear Regulatory Commission

I appreciate the opportunity to talk to you today, and give you what I call a laundry list of activities that has been going on at the Commission over the past year. It has been a busy year. First of all we had to get ourselves organized. At the same time, the Commission has had to deal with several major issues that I thought I would cover briefly. If I have not struck the right ones, please tell me so and we will get into any additional ones during the questions afterwards.

One of the activities that the Commission has been spending a great deal of time on, almost from the time it came into existence in January 1975, is the issue of plutonium recycle--the use of mixed oxide in fuel in commercial nuclear power. The Commission took up this question in January 1975, arrived at a preliminary decision in May 1975, and came out with a final decision on procedures in January of this year. Basically, the Commission has decided to do a full generic environmental impact statement on both the environmental and health aspects of plutonium use in mixed oxide fuel and the question of safeguards. When you hit safeguards, of course, you are hitting one of the four or five main areas of controversy about nuclear power. The safeguards portion of the so-called generic environmental impact statement should provide a comprehensive description of the current status of safeguards in existing industry and then will discuss the future of safeguards in a fully developed mixed oxide industry. We hope to have the modified final health and safety statement issued some time in mid-1976. We will go to a hearing beginning shortly thereafter, to be followed up by issuance of supplemental statements on safeguards towards the end of 1976. The Commission decision on the use of mixed oxide fuel should be available by late 1977 or early 1978.

The second major area that has occupied a good deal of the Commission's attention, and we covered part of that this morning, was on waste management. Before we get to NRC's role in this area, there is a whole series of steps that must be taken by other Federal agencies. ERDA, the Energy Research Development Administration, is the principal agency that has the burden of identifying the appropriate technology. A giant step in achieving this will be the publication of the "Technical Alternatives Document," by the spring of 1976. Following up on this will be a conference in Denver in June, in which the TAD will be the subject of public discussion. Following that meeting, ERDA will issue a draft programatic environmental impact statement for public comment some time around the end of 1976. Working concurrently on this process, the Environmental Protection Agency is developing a general environmental standard. NRC then comes into the process with its own environmental impact statements and its own regulatory rules which should be in place by early 1978. During the course of this buildup, and, again, I think this is where the States come very much into play, is the development of proper goals and objectives for the regulatory programs in the area of waste management. In the past two weeks, we have held a meeting with the representatives of various States in Denver under the leadership of Bill Bishop, who is head of our waste management branch. It was quite a lively session. A diplomat would describe it as a free and frank exchange of ideas on who is to do what in the area of waste management. Certainly, there is plenty of room for both Federal agencies and the States to be involved in this critical area surrounding nuclear power.

Next, I want to talk briefly on the subject of emergency preparedness and emergency planning. I see the meeting schedule indicates that this will be discussed in depth on Wednesday morning. The whole area of emergency planning has come very much to the attention of the Commission. It has come vividly to mind as a result of the so-called Hanauer Report--a special report on the Browns Ferry fire. We are going to hear more about that on Wednesday morning and I won't get into it now. But in addition to the example of Browns Ferry, we have had a number of petitions from public interest research groups concerning the holding of exercises and the testing of emergency plans. We have also had a General Accounting Office report on the subject of emergency preparedness. There are two basic conclusions or recommendations from the GAO Report that I would like to just mention. One, is that the NRC should issue periodic reports on emergency plans to Congress. There have been some discussions between the staffs of GAO and NRC on whether we should actually issue a separate report or whether we could cover this subject in our agency's overall annual report. This is something on which we can easily reach agreement. The GAO also recommended that the Nuclear Regulatory Commission should place personnel in the NRC regional offices to assist the States and work with the States in their emergency planning efforts. As you may or may not know, NRC is quite a centralized agency with most of our activities located in the Washington, D.C. area. The regional offices that NRC maintains are basically regional inspection offices. The Commission has taken up this recommendation of the General Accounting Office and has told the executive director to make a full-scale review of the whole role of NRC regional offices, looking at what additional agency functions could be delegated to them. The question of delegating additional liaison functions with the States will certainly be discussed in detail in this study.

While on the subject of emergency preparedness, I would just like to mention some of the training courses that we have been running through our Battle Creek training program. We regard this as one of our very successful programs. Eight courses have been conducted at Battle Creek. Approximately 225 State and local radiological health and civilian defense personnel have attended these courses. We intend to keep these courses going. We have another one scheduled May 17-21 in Denver, Colorado; another on June 7-11 in Battle Creek; and another one in Battle Creek, in September. If there are additional interest and questions on this, I would appreciate it if you would direct your specific questions to Doc Collins, the Assistant Director of State Programs for NRC, who is responsible for this program.

We have what we call a cadre operation which is an interagency group made up of Federal agencies including EPA, NRC, FDA, and the Bureau of Radiological Health. The cadre made 25 visits to 16 States in the past year and it included involvement of the cadre either as a reviewer or observer of six exercises held at nuclear facilities throughout the country. We are getting recommendations back from the cadre group. Generally the area of most concern that the cadre has expressed regarding the holding of emergency exercises in nuclear power plants revolved around the need to improve communications. Doc Collins, who will be appearing later in the program will describe in some detail what we are doing to followup on this need.

While on the subject of the training programs of State personnel supported by NRC, I would like to cover a few that are not in the emergency planning area. Four of these courses are regular courses--medical use of radionuclides given at the Medical School at Baylor and the Medical School of Georgetown University; a course of regulatory practice and procedures which we run at NRC Headquarters; the NRC course on inspection procedures for nuclear power plants to be given at Oak Ridge; and a 10-week course on health physics and radiation protection. We have been asked by the Agreement States' Directors to carry out two additional courses, one on safety aspects of industrial radiography and a course on management of radiation control programs. Both of these courses will be given by the

Commission. We are working on the development of a curriculum and the details for review by the Conference members and the Agreement State Directors.

When it comes to the subject of Agreement States, there is both interest and controversy. I see a number of workshops scheduled on it for this meeting. We have now 25 states in the Agreement States program that regulate more than half of the radioactive material licenses in the United States. The Agreement State Program is carried out under the authority of section 274 of the Atomic Energy Act. That section clearly defines areas of regulation to be regulated by the Federal government and those areas that could be regulated through an agreement by the States. There are questions on both sides about the future of the Agreement States Program. Certainly some of the discussion of the Agreement States Program now simply involves the Constitutional question of who has the final authority over the regulation of nuclear power. This question has entered into some of our negotiations with the States. I do not think I want to get into this discussion right now before this group, because it is on the agenda, and we are all quite interested in how the discussion comes out.

In response to the request of the State Radiation Program Directors and the Agreement States, we have organized what we call the NRC Task Force for Review of the Regulation of Naturally Occurring and Accelerator-Produced Isotopes. The objective of this Task Force is to assess the need for and the feasibility of the Federal government as opposed to the States regulating this type of radioactive materials. The Task Force that we have organized includes the members of the Association of State Program Directors and Agreement States representatives, FDA, and the Bureau of Radiological Health. The initial meeting of this Task Force was held in Bethesda on April 9, and we hope to have a final report out to the membership of the Task Force and to our own Commission by September 1.

There are two other issues I would like to review with you now. The State/Federal Siting Conference which we will hold in Denver on June 16-18 is an annual conference that we are cosponsoring with the National Governor's Conference. We would like to see both policy and technical officials from State governments attend this conference. Discussions and workshop sessions at the conference will cover issues such as emergency preparedness and the socioeconomic impact of nuclear power plant and fuel cycle plant siting. Early site review process has recently been adopted by the Commission as a policy for proposed rulemaking, and it should form the basis for a great deal of worthwhile discussion at the conference. The objective of this conference is to provide a forum where the States, NRC, and other interested organizations can discuss current issues associated with the siting of new facilities--mainly designed around getting around the old issue of duplication of Federal and State review for the same issues.

Finally, let me close with a strong endorsement from NRC that our involvement with the Association of Radiation Control Program Directors is a most successful program. We at NRC intend to maintain our support of the Association, both in terms of financial support and providing of personnel to assist in task forces of the Association.

Thank you for inviting us to the committtee meeting today. We think it is a very effective way for the NRC to coordinate its activities with the States on nuclear regulatory matters and with the States on the whole question of radiological health programs.

REPORT ON FEDERAL RADIATION PROTECTION ACTIVITIES - PART II

William D. Rowe, Ph.D.
Deputy Assistant Administrator for Radiation Programs
Environmental Protection Agency

It gives me great pleasure to be here once again. It has been 2 years since I spoke to you last. I was unable to make it last year because of some personal problems. As I stand here and look out, I see the same faces, and I think that in about 2 years, the average age of this group has increased by about 2. I have asked myself why?

First of all, it could not be training. The Feds are usually the ones that screw things up but we have dropped out of training; what next? It occurred to me that maybe we have big Federal agencies springing up in Washington so fast that they are hiring all the people away at big salaries. I an not so sure about this, but it might be the case. It could also be that budgets at the State level are pretty stiff these days, and only those with seniority get to come.

But, regardless of the reason, I am left at a disadvantage; having spoken to you before, you all know my jokes, so I can't tell them to you again, and secondly, I have said the same thing to you for, I think, 5 meetings. All I can do at this time, really, is update areas where changes have taken place in the last 2 years.

What has really changed in that 2-year period is, I think, an increased emphasis of EPA towards its Federal radiation protection role; namely, radiation protection across the board. Now, what does this mean? I saw a cartoon which I think best sums it up once and for all. What is says in the first frame is, "The nuclear power plant in your town is completely safe, sir. Those environmentalists don't know anything about radiation hazards." The next picture says, "It is a very complex subject. Heavens! Even those of us in the agency don't really know what the permissible levels should be. Yes.... Yes.... Bye.... Bye...." And the last balloon says, "One more citizen given peace of mind."

In a sense, I think part of our role is that the agency looks across the board at all aspects of radiation in implementing our authority transferred from the former Federal Radiation Council. One of the difficulties involved is that we get different groups of people looking at the same problems, but they look at the same problems in different ways. As I listened to the discussion here this morning and the earlier part of this afternoon, I reviewed a thesis that Bob Kates of Clark University has proposed. He says that there are three different kinds or groups of people who review risk data and associated problems. The first of these groups are people who say that the actual risks are always worse than stated; Kates calls these people the "tip-of-the iceberg" group. Another group believes that the actual risks are never as bad as stated; these he calls these the "count-the-body" group. Finally, Kates says that there is a group who feel that that actual risks are different than those stated, but they don't know in which way or why. He calls these people the "worry bead" group. EPA is in the "worry bead" group. We don't know what the actual risks are in many cases; we know that people have made certain claims and we don't know what the balances are. So we go about trying to find out what they are. We do this first of all by making measurements to find out what actually is going on in the environment. We conduct research and see what the health effects are; in this area, Dr.

Hilberg has told us nothing much has changed in the past few years, and if it does change, it will change slowly.

We then look at the technologies that control risk and make risk/benefit analyses, and eventually we come out with standards, which we then try to implement. This is the business that EPA is involved in—trying in an open, credible way to tell people that a level of risk is good enough, or if it is not good enough, why not and what we can do about it.

In accomplishing this process, we have had a number of different programs. I think you have heard about these programs before. All I am going to do is to update them a bit.

In the area of standards, the first one that is coming through to you is our drinking water standard; it should be published in the FEDERAL REGISTER sometime in May. The difference in the drinking water standard in final form from the proposed standard is a change in the monitoring regulations. They have been changed in such a way that the monitoring system is more economical; I am sure you will all be glad to know that. We think that the new regulations are reasonable to monitor. I don't want to discuss them in detail now; you will see them in about 2 weeks.

The second effort is that of the uranium fuel cycle. As you know, we had hearings on this 2 months ago and we are now going through the results of those hearings; we are looking at new information, making some further studies, and hope sometime this summer to promulgate it as a final environmental standard for the uranium fuel cycle. The time schedule will depend upon the promulgation and how we meet with other agencies to resolve issues.

Also in the next couple of weeks, final water quality criteria will be issued under the Water Quality Act, which includes some levels of radiation.

We have been working on Federal guidance standards in a number of areas. We are developing and issuing Federal guidance, using the help of a series of interagency committees. In other words, we are not working on Federal Guidance alone; but through a consortium of Federal groups in each area. In most cases, we have State representatives on a group, as well as others from industry and the public. Most of our meetings are open meetings; they are announced in the FEDERAL REGISTER, and we welcome State participation. In addition, we have a number of members of the Conference of Radiation Control Program Directors working with us on some of these groups.

One of the first criterion that will be coming out, within the next month or two, will be a draft report for standards for the cleanup of plutonium. This is a standard that I know people in Denver have been waiting for for a long time. It is one that the agencies have been working on together and will be reviewed by them prior to issuance of guidance on cleanup of plutonium.

We have also been involved in Federal guidance looking at radon from the phosphate industry in Florida, Idaho, and other places. We will be coming out with interim guidance on the phosphate industry very shortly, and then we will be coming out with final guidance about the end of the year. In the meantime, under the Water Quality Act, we have set up effluent guidelines for the phosphate industry.

One aspect of the Federal guidance function, was completed this last year when we published and circulated our first report on Radiation Activities in the United States for 1974. The second report covering 1975 will be released in about a month. This has been a coordinated effort of all the agencies involved in radiation protection plus the States' efforts through the Radiation Control

Program Directors who have input through Don Gilbert--our representative on that group. The report on radiation activities in the United States will will be published annually.

Another aspect of Federal guidance in the offing is our work with the various agencies involved in developing new occupational guidance. When I say "new," it doesn't necessarily mean that numbers will change. What we are doing is looking at that whole guidance and updating the recommendations. We don't know what they will be yet, but in the very near future, we will be making recommendations on occupational radiation guidance.

In the x-ray area, most of you have probably already seen our "orange" report on the prescription of x rays that is out for comment and a second report on procedures and technic for x rays will be published very shortly. We would like very much to have your comments back on this report as well. Jim Martin will be talking about these issues in more detail. We will be looking forward to your comments on the report.

Bill Dircks mentioned that there is a Federal effort going on in waste management. I think it is very important. We heard today that there are no technical problems that are unsolvable in the waste management area. In general, I think that is probably true, even though we have a way to go to make sure that this really is the case. The problems, I think, are institutional ones. The first institutional problem is creating a coordinated Federal program to do something about waste management, and I think this is what is in the offing. I think it is going to be a coordinated effort; it is not going to be an easy one, but it is underway. Just as we have gotten cooperation among Federal agencies in the areas of Protective Action Guides and emergency response, I think we are going to get a similar meeting of the minds in the waste disposal area. When I talk about waste disposal, I don't just mean high-level wastes, I mean the transuranics; I mean low-level wastes; I mean problems in decommissioning; I mean ocean dumping; and I mean mill tailings--whether uranium or vanadium or anything else. These are all waste disposal problems, and the low-level waste problems are even nearer term than the high level ones. I think management in certain States is well aware of that. Even the best institutions do not go very fast, and I think we are all frustrated, because things never go fast enough when we have many different groups of people working in these areas. At least we will be working, hopefully, in the same direction now.

A new EPA effort is the undertaking of a shelf of radiation problems in energy sources other than nuclear.We've been working with some of these sources for some time, but we have not consolidated the efforts into a total program. Initial efforts have involved geothermal energy processes and involve looking at the distribution of natural radiation in these sources. We have also been doing the same thing in the fossil fuel area, where we have been looking at natural gas and coal; realizing that some of the western coals also are uranium grade ore. We do see some problems in the redistribution of natural radiation.

In regard to emergency response planning, our Protective Action Guides are going to be updated, Federal guidance is forthcoming on the guides, and there will be further guidance coming out as soon as possible. Eventually, our manual can be completely updated. We hope it has been a help, and, of course, we will get your feedback as to your emergency response needs.

Our monitoring efforts have now been capped by a new approach and we hope the first report will be out in the next month or month and a half. We have put together, with the help of other Federal agencies, a report on the Radiological Quality of the Environment. We hope that this will be an annual report, coming up with all the monitoring information on radiation from all sources in one place. The first report, we have found, has been a means of uncovering the deficiencies in existing data, and where data is unavailable in the form we would like to have it. We have made at least a first attempt to bring together this data. When you see the first report, I think you will find it useful, although I also think you will find many gaps. At least we know now where to concentrate our effort and who to work with to try to fill in some of these gaps. Let me say that the State data and the people who are working with the data on the ERAMS program have really been the backbone of much of the environmental data to date. This seems to be the best baseline that we can use for handling data.

Our nonionizing radiation program has been continuing our mobile measurement operation. We have already gone through Boston; Philadelphia, I believe, is next. We also have been in Atlanta, Miami, and a couple of other cities where we now have some profiles of the total electromagnetic radiation spectrum in these areas and we will be publishing these data soon.

The final thing I want to talk about is what probably is of most interest to you--how our program is going to be cut back in State aid. As you know, EPA, under OMB edict, has taken a 10 position and a half-million dollar cut in our budget for fiscal 1977--specifically in the area of assistance to States. We are now programmed to cut back directly on assistance to States.

We hope that we will not lose all joint effort between EPA and the States in the area of support. You may not agree with everything we do, at least we found a way to work together and help each other. I think this exchange is perhaps one of our most significant areas of contribution where we act as an independent measuring agency, and we can work with you to make sure that independence is extended to you. This has been a very important part of our program, and we are trying to insure that what we do is credible so that we don't have to sit back in our chair and have our own balloons going up saying, "Here's a satisfied member of the public." At least, we can say that we have really satisfied most of them.

REPORT ON FEDERAL RADIATION PROTECTION ACTIVITIES - PART III

John C. Villforth

Director
Bureau of Radiological Health, FDA

One of the purposes of our presence at this meeting is to learn and profit from each other's questions and answers. Over the past years, this exchange has been most beneficial for all of us at the Bureau of Radiological Health.

I want to assure you that the Food and Drug Administration is continuing to receive support for radiation activities. We are very pleased for the support, whether it is for the Executive Director for Regional Operations activity, or for other elements of FDA, or for the Bureau of Radiological Health.

Some of you have expressed concern over the interaction between the Bureau of Medical Devices and the Bureau of Radiological Health once the medical device legislation is passed. The best way to explain the interaction might be to read to you from the response that the Commissioner gave in reply to the same question presented to him at the recent meeting of the Technical Electronic Product Radiation Safety Standards Committee. Dr. Schmidt said:

> There are a number of concerns expressed to me--a number of ideas ranging all the way from this Bureau (**Bureau of Rad Health**) implementing the Devices Act for certain kinds of products. I have concern that the regulation of these products is done effectively and efficiently without any conflicts between the Bureau of Medical Devices and the Bureau of Radiological Health. We will have joint administration of the Devices Act by the two Bureaus. There will be a working group established with members between the two Bureaus in frequent communication and consultation, and ways worked out so that there will not be conflicts in development.

Dr. Schmidt points out that as far as FDA is concerned, there are many situations where the activities of one Bureau involve the activities of another, and this has worked out successfully in FDA. In addition, he said:

> As I have reviewed the range of products and legislations and so on, I think it is very clear that the two Bureaus are going to have to work very closely together, and there will probably have to be a guy that, in between tasks, is specifically charged with ensuring that all of the communications about policies, programs, enforcement, the whole business--so that the bad things that could happen will not happen. If it does not work, then I will do something else. But, the first step will be to gather a working group from both Bureaus.

I think it is quite clear that Dr. Schmidt gave us a mandate such that the Bureau of Medical Devices and the Bureau of Radiological Health are going to have to work rather closely together.

The Food and Drug Administration is supportive of the concept of State contracts and supportive of the work of this Conference. I think the value of this type of conference to the Agency is quite clear, and it will continue. This Conference is a most important milestone, and a success to you for having identified your ability to work with us--the ability to bring those of us together at the Federal level to meet the same problem.

Another question recently raised about the Food and Drug Administration's role has been how does a regulatory organization deal with the educational programs. The Bureau of Radiological Health has been working with programs to promote and encourage fair medical practice through training, and so forth. The educational activities of the Bureau have been given the endorsement by the Commissioner to move ahead. Dr. Schmidt supports all the educational activities of the Bureau, and this is consistent with those activities that he believes are the role of FDA.

Most of you are familiar with what we are doing in the compliance or standard setting area. You know that we have the Laser Performance Standard that will go into effect this August. We continue to meet with the Technical Electronic Products Radiation Safety Standards Committee. And, of course, you should be extremely proud of the fact that you have two representatives, Mr. Tom Gerusky and Mr. Jim Porter, who are members of this 15-member technical committee.

In addition, we have some proposed standards under consideration that I would like to summarize for you. A standard for microwave diathermy equipment is presently in the developmental stage. The intent of this standard will be to minimize the amounts of scatter microwave energy to the patient or the operator; this provides the operator a means of knowing the microwave output of the device.

Also under consideration is the standard for ultrasound therapy devices, to be published in the **FEDERAL REGISTER** shortly as a proposed rule. The basic intent of this standard will be to specify accuracy limits of the power output controls and to accurately describe the ultrasound output from the applicator. These requirements are necessary for safe and efficacious use of the equipment.

We, particularly, believe that the standards for sunlamps and mercury vapor discharge lamps are needed. The number of injuries from these products is substantial and the injuries are extremely painful with possible permanent effects. The sunlamp standard is soon to be published in the **FEDERAL REGISTER** as a proposed rule. For this product we will attempt to require timers, minimize certain frequencies not required for tanning, and improve user instructions and labeling. We are taking a different approach, for the standard for mercury vapor discharge lamps. We will be working with the American National Standards Institute, Committee C78.4, rather than the regulatory performance standard approach. We feel that we can get a standard in effect through ANSI much faster than we can through a regulatory performance standard. This will allow us the opportunity to continue to take compliance action against the manufacturer under the "defect" provision of the act. This is an experiment to see if we can work with organized standards setting groups like ANSI and achieve proper radiation protection. If ANSI should fail, we are totally and completely prepared to proceed with a regulatory performance standard. However, if we can succeed with the cooperation of the American National Standards Institute, this may have some very salutary effects.

As a final note in the regulatory area, I want to point out that the FDA is promulgating administrative procedures for the enforcement of civil penalties that are authorized in the Radiation Control Act. Up to now, we have not levied any financial penalties, which by the way are $1,000 for one violation and up to $300,000 for one person responsible for a series of violations. We believe now, however, that the levying of these penalities will be an additional deterrent to those individuals who contemplate violating the regulations.

In addition to all of the activities of setting performance standards and considering new areas of involvement, we have to be constantly fine-tuning those standards which are already in the books. Concern has been expressed and questions have been raised regarding the positive beam limitation and the need to reevaluate their efficacy. In March 1976, we sent a letter to manufacturers of diagnostic x-ray equipment, asking them to provide information as to whether or not amendments to the standard are necessary, if the Bureau should place a different emphasis on the user/operator training programs, and whether our cost/benefit projections are adequate. A great deal of the concern expressed by you has to do with the question of cost/benefit analysis. We do not intend to ask the questions of industry alone, but we feel that we must start there because industry certainly holds much of the data on the cost/benefit analysis.

Similar to the regulatory performance standards are the aspects of guidelines and recommendations. You already heard mentioned the Gonad Shield Guidelines that are soon to be finalized and the X Rays in Pregnancy Guidelines that have been sent out for comment. Dr. Nader pointed out that we should be moving faster in this area; but it takes quite a bit of time.

We are also considering quality assurance guidelines for medical radiation, and an advanced notice should be published this week. We hope that by November we will have an opportunity to receive comments in response to the questions stated in this notice.

The guides and recommendations evolved in a similar fashion as did the regulatory performance standards. We,therefore, must take into consideration all of the benefit/risk and cost/benefit analyses, and provide adequate documentation so we do not end up being capricious and arbitrary in our guides.

Another area has to do with the collecting of information with which we can make programmatic decisions. We have had ongoing for 3 years now the Nationwide Evaluation of X-Ray Trends (NEXT). I believe there are some 23,000 different examinations in the data pool that will your State with the norms around the country. This program is continuing and is being expanded with additional information collected on image receptors. This is a vital, exciting program, and it continues to provide a very valuable data base.

The DENT program, or Dental Exposure Normalization Technique has been very effective. I think those of you who have been involved with the program have had the satisfaction of knowing that the dental x-ray exposures have dropped markedly in participating States. The mean dental exposure before the DENT program was something like 600 milliroentgens per film. Afterwards, exposures dropped to something like 340 milliroentgens per film. This type of success, this type of satisfaction in the dental area is tremendous.

Mammography is another area of concern to us. We hope to have data bases for mammography that will allow the same type of assessment in the mammography area as in the dental area.

In the nuclear medicine area, we have been collecting data through the resources of the Associate Commissioner for Planning and Evaluation, FDA. This is the program called MODS, the Medical Oriented Data Systems. We have obtained baseline data from at least six hospitals around the country on trends in nuclear medicine. The future of this survey is somewhat uncertain, but we hope that we can continue with support to get data on nuclear medicine trends in this country.

The collection of data only leads to the need for action programs, and that is what radiation protection is really about. The data does not in itself solve problems or reduce the dose--it just provides direction. One of the most exciting action programs that we are about to initiate is Quality Assurance in diagnostic radiology. Although we have talked about this for some time, there has been more State activity in this area than some of us may have realized. For example, 35 States have been collecting some sort of information on x-ray darkroom integrity to see if light leaks may cause fogging of the film. Excess film fog can degrade the information on the film or may result in retakes. I might mention that the DENT program is a type of quality assurance effort. So, most of you actually have been thinking about some aspect of quality assurance. Now, we want to put this together with other techniques, to evaluate all the different mechanisms and tools in areas of quality assurance, and provide this to you.

The Bureau has sponsored a symposium with the American College of Radiology on film/screen combinations. Mismatched film and screens are the cause of poor radiographs, and if we can use the advise of respected clinicians to recommend the acceptable and the best combinations of films and screens for specific procedures, we can help improve the quality of the final product. To help our staff appreciate the complexities of a working department, we have been applying some quality assurance efforts in the Baltimore PHS hospitals. After 6 months of operating a quality control program there, we were pleased to find that by just controlling the automatic processor temperatures, we were able to reduce the exposure in diagnostic radiology by about 15 percent and reduce the number of retakes by about 40 percent. Once you get into a quality assurance program you are able to see a rather rapid positive reduction in dose.

In order to evaluate the impact of all of these active programs, we need a better understanding of the specific organ doses in diagnostic radiology. One of the things that we were criticized for in the middle 60's, right after we started the X-Ray Exposure Study in 1964, was that we did not have a model to determine the organ doses that could result in somatic consequences. We did have the gonad dose model, but we did not have the significant doses that were helpful for us to evaluate some of the somatic effects of radiation. We are pleased that we now have two models in operation for bone marrow. One model is a modification of the United Kingdom model worked out by Dr. Bernard Schlein. We have been able to run some preliminary numbers for the X-Ray Exposure Studies of 1964 and the X-Ray Exposure Studies of 1970 which will be published soon.

Dr. Marvin Rosenstein has taken a quite different approach using a modification of the Monte Carlo model developed at Oak Ridge. His approach will allow you to determine doses for bone marrow, lens of eye, thyroid, and so forth. We will soon make available a small handbook which you can use in determining these organ doses. For example, this will be helpful if a radiologist finds a woman who received some x-ray examination of the abdomen and later was reported to be pregnant. With this handbook, you can go back and find out what the dose was to the fetus. These are very important tools and I just want to emphasize them.

In the new areas, questions about mammography and CT scanners are beginning to be asked. Dr. McDonnel ably covered his concerns regarding CT scanners. The Assistant Secretary for Health, Dr. Theodore Cooper, recently told us that the cost of health care in this country is something like a hundred billion dollars. The question we have now, he said, is to find out the full impact of all of the different processes contributing to the cost of health care. He singled out the CT scanners as one of the items that should be looked at. We do not know what direction, from an FDA standpoint, we should go with the CT scanners. Do we look at performance standards? Do we look at the efficacy of use? Do we look at the training of the technologist? Do we study the dosimetry? In fact, we are studying all of these and are trying to learn as much as we can about all questions for CT scanners.

We probably would still be a year or 6 months, at least, behind if it had not been for those of you who raised these questions about CT scanners and mammography; if it had not been for New York City that raised questions about "storefront mammography;" if it had not been for the State of Pennsylvania who had gone out and made some exposure measurements in mammography, or Massachusetts who raised some questions on the efficacy of mammography screening. If these questions had not come to us, I am afraid we would be much further behind than we are now.

We are looking at the whole issue of quality assurance in mammography--the best techniques and the best applications. We will soon be publishing a notice in the **FEDERAL REGISTER** about quality assurance in mammography. Efficacy of mammography screening of asymptomatic women is another issue of importance. Our Division of Biological Effects has prepared a paper on this, which we have sent to the American College of Radiology, the National Cancer Institute, the American Cancer Society, and the American College of Preventive Medicine, asking for their opinions and suggestions. We hope we can sit down and work out a national position on screening of asymptomatic women.

Finally, all of our activities must be communicated back and forth with you. We no longer have the extensive short course training programs that we had a few year ago. We miss the opportunities they provided to maintain a rapport with you. How do we bridge the gap left by the short course training? How do we assist you in your State programs, provide input to new people coming on your staff? How do we provide the "old timers" in radiological health with new information such as Dr. Jerry McDonnel presented on CT scanners? We are trying to see if we cannot bridge some of this gap with the use of videotapes and training packages. In order to give some emphasis to this, we are setting up in the Division of Training and Medical Applications an Associate Director for Training Coordination to provide a central focus in the Bureau for communications. Mr. Richard Peterson, who was formerly with the Electro-Optics Branch, Division of Electronic Products, will take on this responsibility. We feel our videotape library concept is an exciting one. We would like your suggestions, and see if this technique can be of help to you.

I would like very much to see a re-examination of our present system of communicating through the Conference task forces and workshops. My concern is that as new problem areas develop--almost overnight--e.g., mammography, CT scanners--we need a more rapid, a more responsive way to communicate with the Conference. I would ask that the executive officers of your Conference give some consideration to new ways of communicating so that when we have problems and we have concerns for things that are on the horizon, we can work very rapidly with you and not have to wait until next year to set up a task force or a workshop. "Future shock" in rad health is with us.

As always, I appreciate the opportunity to be here--it is a learning process for all of us. Those of us in the Bureau and the rest of FDA are delighted to be a part of this Conference.

TASK FORCE REPORTS

Moderator: *Robert C. Will*, Washington

EVALUATION AND DISTRIBUTION OF RADIOACTIVE SOURCES AND DEVICES NOT MANUFACTURED UNDER THE ATOMIC ENERGY ACT
Edgar Bailey, Chairman, Texas

MEASUREMENT OF PROGRAM EFFECTIVENESS AS RELATED TO RADIOACTIVE MATERIALS
Goldie Watkins, Chairperson, New York

NATIONWIDE EVALUATION OF X-RAY TRENDS
Joseph O. Ward, Chairman, California

SUGGESTED STATE REGULATIONS FOR CONTROL OF RADIATION
Charles Froom, Chairman, Maryland

NATURAL RADIOACTIVITY CONTAMINATION PROBLEMS
Ulray Clark, Chairman, Florida

RADIOACTIVE WASTE MANAGEMENT
Heyward G. Shealy, Chairman, South Carolina

BONDING AND PERPETUAL CARE OF NUCLEAR LICENSED ACTIVITIES
A. J. Hazle, Chairman, Colorado

STANDARDIZATION OF RADIATION MEASUREMENTS
Thomas M. Gerusky, Chairman, Pennsylvania

COMMUNICATIONS
Donald C. Gilbert, Chairman, Arizona

SESSION: EVALUATION, STANDARDS, AND GUIDELINES IN DIAGNOSTIC RADIOLOGY

Moderator: *Thomas M. Gerusky*, Pennsylvania

THREE YEARS OF NEXT--AN ANALYSIS
Ralph Bunge, Acting Chief, Analysis and Evaluation Branch, Division of Training and Medical Applications, Bureau of Radiological Health, Food and Drug Administration

IS THERE A NEED FOR NATIONAL RECOMMENDATIONS ON THE QUALIFICATIONS FOR MEDICAL RADIATION
Norbert P. Heib, Jr., Acting Chief, Allied Health Branch, Division of Training and Medical Applications, Bureau of Radiological Health, Food and Drug Administration

DISTRICT OF COLUMBIA'S EVALUATION OF THE ADMISSIONS, PRE-EMPLOYMENT, AND ANNUAL CHEST X RAYS

Richard Lane, Chief, Bureau of Occupational and Institutional Hygiene and Radiological Health, Environmental Health Administration, District of Columbia

ILLINOIS' PATIENT EXPOSURE LIMITS--AN UPDATE

Maurice Neuweg, Manager of Compliance, Division of Radiological Health, Illinois Department of Public Health

EPA'S FEDERAL GUIDANCE ON MEDICAL X RAY

James E. Martin, Ph.D., Deputy Director, Criteria and Standards Division, Office of Radiation Programs, Environmental Protection Agency

MINNESOTA'S SCREENING REGULATIONS

Alice Dolezal, Chief, Section of Radiation Control, Minnesota Department of Health

SESSION: DIAGNOSTIC RADIATION REDUCTION AND CONTROL

Moderator: *Alice Dolezal*, Minnesota

RADIOLOGY QUALITY ASSURANCE OVERVIEW

William Properzio, Ph.D., Assistant Director, Division of Training and Medical Applications, Bureau of Radiological Health, Food and Drug Administration

RESULTS OF WEST VIRGINIA'S QUALITY ASSURANCE PROJECT

Beattie DeBord, Radiological Health Specialist, Radiological Health Program, West Virginia State Department of Health

QUALITY ASSURANCE TEACHING PROGRAM FOR NUCLEAR MEDICINE TECHNOLOGISTS

Richard J. Van Tuinen, Chief, Quality Control Section, Nuclear Medicine Laboartory (Cincinnati, Ohio), Division of Radioactive Materials and Nuclear Medicine, Bureau of Radiological Health, Food and Drug Administration

IMPLEMENTING QUALITY ASSURANCE IN NUCLEAR MEDICINE

Peter Paras, Ph.D., Director, Division of Radioactive Materials and Nuclear Medicine, Bureau of Radiological Health, Food and Drug Administration

INTERFACING JCHA NUCLEAR MEDICINE STANDARDS WITH NUCLEAR MEDICINE LICENSING REQUIREMENTS

Goldie Watkins, Chief, Radioactive Materials Licensing Section, Bureau of Radiological Health, New York State Department of Health

BUREAU OF RADIOLOGICAL HEALTH'S COMPLIANCE PROGRAMS--AN UPDATE

Robert G. Britain, Director, Division of Compliance, Bureau of Radiological Health, Food and Drug Administration

INFORMATION SPECIALISTS' ROLE IN STATE RADIATION CONTROL PROGRAMS

Richard Ridgway, Chief, Public Affairs, Illinois Department of Public Health

TASK FORCE NO. 1

EVALUATION AND DISTRIBUTION OF RADIOACTIVE SOURCES AND DEVICES NOT MANUFACTURED UNDER THE ATOMIC ENERGY ACT

Edgar D. Bailey, Chairman - Texas
Allen C. Tapert, Secretary - BRH
James A. Blackburn - Illinois
Kirk Whatley - Alabama
Eddie S. Fuente - Mississippi
James E. Hickey - Rhode Island
Edgar C. "Jim" Ashley - NRC
Joseph E. Fitzgerald - EPA
Charles Froome - BRH

Upon the recommendation of Workshop No. 7 of the 7th Annual National Conference on Radiation Control, the Executive Committee of the Conference appointed Task Force No. 1 and charged it:

"To develop the criteria needed to perform an adequate evaluation of devices, sealed sources, foils, dials, and matrices which contain naturally occurring or accelerator produced radioactive material (NARM) and factors regarding their interstate distribution. By means of these criteria to provide a mechanism for State-Federal control of the manufacture and distribution of subject sources and products not covered under the Atomic Energy Act."

Toward meeting these goals, the Task Forces met five times, twice in Atlanta, Georgia, and thrice in Rockville, Maryland. As a result of these meetings 13 specific NARM Guides and an Introductory NARM Guide were written and distributed for review and comment. The comments received through the time of our March meeting were reviewed, analyzed, and incorporated into the draft edition of the Guides that were mailed to each State last week and were at the table clinic last night. In addition, a reference document containing all the comments and the Task Force's analysis and action on each comment has been written and will be sent to each person who submitted comments on the draft Guides.

For those of you who still wish to comment, and the members of the Task Force sincerely hope that you will, the comment period is still open.

I would encourage each of you to pay particular attention to the Introductory NARM Guide because it is the one that makes the entire proposed NARM system of evaluation and regulation succeed or fail. The salient features of an effective nationwide system for the uniform evaluation and control of products containing NARM are spelled out in the Introductory NARM Guide:

"The NARM Guides are the basis of a program aimed at attaining uniformity in the evaluation and distribution of NARM sources and products through the cooperative efforts of the States and BRH. These guides provide for the uniform classification and evaluation of NARM Sources and products by radiation control agencies and are intended to be used in conjunction with the Radioactive materials Reference Manual (RMRM) and the Suggested State Regulations for Control of Radiation (SSRCR).

"The NARM Guides will also provide assistance to manufacturers, assemblers, and distributors regarding radiation safety aspects for NARM sources and products.

"Uniform application of the NARM Guides by radiation control agencies will promote radiological safety in the manufacture, assembly, and distribution of NARM sources and products. Each NARM source or product intended for distribution in the United States shall be evaluated according to the appropriate NARM Guide prior to distribution.

"An Agreement State or Licensing State shall determine that each NARM source or product has been evaluated in accordance with the NARM Guides prior to licensing its possession and use. The issuance of a RMRM evaluation sheet is evidence that such an evaluation has been performed. The distribution of NARM sources and products shall be licensed in Agreement and Licensing States. Other States shall issue a 'Letter of Authorization' (or other document) which establishes that an evaluation of the NARM source or product has been performed and that its manufacture, assembly, or distribution is being performed in accordance with the applicable provisions of the SSRCR.

"The evaluation of NARM sources and products may be accomplished as follows:

1. State only - A State may, at its discretion, identify, evaluate, and prepare RMRM evaluation sheets on any NARM source or product that is manufactured, assembled, or distributed within its jurisdiction.
2. State with BRH assistance - A State may at its discretion, request assistance from BRH for a cooperative evaluation of a NARM source or product of a manufacturer, assembler, or distributor within its jurisdiction. This request shall be in writing.
3. BRH at the request of a State - A State may, at its discretion, request BRH to perform an evaluation of a NARM source or product of a manufacturer, assembler, or distributor within its jurisdiction. This request shall be in writing.

The evaluating agency shall require the manufacturer, assembler, or distributor to submit in writing all information specified by the appropriate NARM Guide. In the event that a product or device contains a source which has previously been evaluated and included in the RMRM, no further evaluation of the source need be made providing the proposed source use is specific to that of the previously evaluated source.

A State shall not issue an RMRM evaluation sheet on a NARM source or product that is not acceptable for routine distribution under the suggested level of regulatory control.

A State shall not evaluate a NARM source or product being manufactured in, assembled in, or distributed from another State."

In writing the NARM Guides and reviewing your comments, the Task Force discovered three areas of major concern in NARM products:

1. Exempt and Generally Licensed Quantities of Ra-226 - The SSRCR provided for a generally-licensed reference or calibration source of only 1 microcurie. The Task Force recommended to the Part C Review group that this limit be raised to 5 microcuries in order to be identical with the limits for Am-241 and plutonium. This suggestion has been incorporated into the Proposed Charges to Part C. The Task Force also recommended doing away the "grandfathered" exempt Ra-226 sources; this suggestion

was also incorporated. The Task Force also set a limit of 0.1 microcurie of Ra-226 in gas and aerosol detectors intended for exempt distribution and suggested that this limit be established by regulation.

2. Acceptance of Product Evaluation by Non-Agreement States - The hesitancy of some Agreement States to accept the evaluation of a NARM source or product done by a Non-Agreement State which is not subject to review for program adequacy and compatibility was discussed at length. Our conclusions were that this problem is largely an unfounded fear; and that with the NARM Guides and the availability of BRH assistance, NARM sources and products will receive an evaluation of comparable uniformity with that now seen in the Sealed Source and Device Catalogue. At worst, the Task Force feels that any evaluation prior to distribution would be far better than the present situation of no review prior to advertisement, sale, and distribution.

3. Changes to NARM Guides and Regulations - During the Task Force's discussion we came to a realization that there is a need for the establishment of a method for affected individuals - i.e., users, manufacturers, distributors, and so forth - to initiate changes to the NARM Guides and to the SSRCR.

RECOMMENDATIONS

The Task Force recommends that the following actions be taken by the Conference:

1. That after review of all comments and appropriate modification, the NARM Guides be accepted by the Conference and by each of the States as the guidance to be used in evaluating and controlling NARM sources and products.

2. That the Conference develop a NARM Guide for the inspection of NARM product manufacturers, assemblers, and distributors to ensure adherence to high standards of quality control.

3. That the Conference continue Task Force No. 1 in the coming year to finalize the work on the draft NARM Guide currently written and to develop the NARM Guide recommended in 2 above and other Guides as needed.

4. That the Conference establish a mechanism whereby affected individuals may initiate changes in the SSRCR, the NARM Guides, and other Conference recommended policies, procedures, and standards.

5. That the individual Agreement State and Licensing States begin to license medical "sealed sources, plaques, and needles" containing Ra-226 by specific model numbers or designations.

6. That the Conference petition the NRC for rule changes to:

   a. Place limits on the amount of radioactive material in exempt products such as gas and aerosol detectors, and

   b. Place limits on the maximum amount of radioactive amount of radioactive materials in generally-licensed gauges.

7. That the Conference strongly encourage EPA and NRC to allow their employees assigned as resource people to Task Forces to attend Task Force meetings when the Task Force meets out of the Washington area.

In closing, let me express the appreciation of the State Members for the support given to our efforts by the Federal representatives and especially to Al Tapert for total involvement in our work.

TASK FORCE NO. 2

MEASUREMENT OF PROGRAM EFFECTIVENESS AS RELATED TO RADIOACTIVE MATERIALS

Goldie Watkins	New York	Chairperson
Edd Johnson	Wyoming	
Jerry Morris	Georgia	
John Russo	New Jersey	
Ernest Resner	NRC	

The Task Force was established during the 1974 Annual Conference meeting. During 1975, it met three times; once in Kentucky and secondly and thirdly during the 1975 Annual Conference meeting and the NRC Agreement States Meeting, respectively.

Because of the imperative nature of our charge, in September 1975, an NRC-developed catalog for coding generic violations of our regulations was sent to the States for use in analyzing compliance data. Along with the document, an interim proposal was provided for using the NRC "Guide for Evaluation of Agreement State Radiation Control Programs" in looking at what is delivered by a program and how this product is delivered.

Bob Corcoran, Maryland, noted after reviewing these materials that for the most part, the indicators found in the NRC guide could not be measured concretely. He further indicated that the Coding Catalog was good but should be streamlined for State usage. Comments on the material provided were also received from Oklahoma. These were the only two States that provided comments on the material.

During its third meeting, the Task Force decided that the most effective next step would be to seek to accomplish its charge through a contractual arrangement with an appropriate group. However, before this could be pursued, we needed to know:

1. How many States had computerized data base capability; and
2. If such was available, how many States used the system for maintaining current information on their regulatory programs.

A questionnaire designed to yield the information was sent to 51 Radiation Control Program Directors on March 1, 1976. Responses were received from 22. Twelve of the 22 respondees have computerized data base capabilities and of this number only 4 use these systems for maintaining current information on their radioactive materials regulatory programs.

While the above information was being sought, two groups were contacted in terms of ascertaining their capability and interest in assisting us in meeting the charge given to our Task Force. One of these groups, Oak Ridge Associated Universities, responded with a concrete proposal for conducting a feasibility study to determine the associated complexities, budget, suggested methodologies, and time frame of the larger second stage study for developing meaningful indices. A budget for the preliminary study of $29,000 was proposed which would include the assignment of several persons to the project for a total of 9 man-

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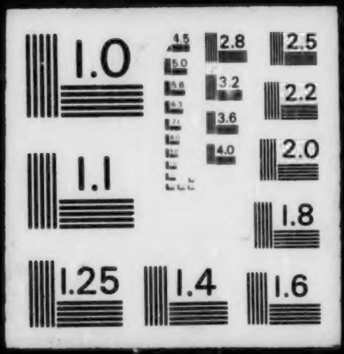
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months of professional efforts. Among these persons would be included a professional researcher/analyst and a health physicist.

The NRC, FDA, and the Conference have been contacted regarding funding of the proposal. Both NRC and FDA have indicated that no funds are available at the present time for undertaking such an effort. The NRC furthermore questioned the appropriateness of 29 percent of the proposed budget for overhead, general administration, and services. Bob Will suggested that the proposal be submitted to the Western Interstate Nuclear Board for consideration. This will be done.

In the meantime, Oak Ridge indicated that it would be helpful to them to know the range of computer capabilities available to the various Radiation Control Programs; therefore, we still need this information from the 29 States that have not responded to the questionnaire to date.

The Task Force wishes to extend its appreciation to the NRC for the assistance provided for its activites which were not covered by the Conference and for the expert consultation provided by Ernest Resner.

The Task Force recommends that the Conference members continue to support its activities and provide guidance and consultation as requested.

TASK FORCE REPORT ON NATIONWIDE EVALUATION OF X-RAY TRENDS

Ralph Bunge
Bureau of Radiological Health, FDA
(For Joe Ward, Chairman)

I am making this report for Joe Ward of California, Chairman of the NEXT Task Force who was disappointed that he could not attend this Conference because of restrictions on out-of-State travel.

The Task Force met this year for 3 days in Rockville and additionally, several decisions were reached by telephone consensus. The main topic of discussion at the meeting was quality assurance of medical x-ray and its relationship to NEXT. The Task Force was concerned that the basic NEXT survey continue to be available without adding required time-consuming procedures.

In this regard, additional information on film, screen, grid, and processor conditions will be gathered as an optional, add-on module to the basic NEXT survey (Image Receptor Module) which a State can use or not use as it decides.

Another major concern of the Task Force was representativeness of NEXT data. If States are going to make program decisions on the basis of NEXT data, they need to know something of the reliability of the data. FDA Regional Representatives are now contacting States to get information on the selection criteria used for NEXT surveys.

Normally included in this annual report is a little about the year's activities in NEXT. One of our major past efforts, the Optimum Survey Procedures Manual published a year ago, has proven so popular that we had to reprint it, and it is again available. The NEXT master file now contains over 23,000 surveys done by 43 States and local agencies in addition to the Federal participants. Foreign country interests include Israel, which is now submitting surveys to us for processing and Italy which is importing the system, computer programs and all.

Several minor changes agreed on in the basic NEXT survey are now being made and we hope to be able to switch over this year.

Finally, talks were given at the NBS Conference, a general report on the system given by John Shaver, and I gave a talk at the Health Physics Midyear Symposium on the analysis of the NEXT data as it shows the need for quality assurance.

In conclusion, it is recommended that this important effort should continue to be guided by a joint State/Federal Task Force in the coming year.

REPORT OF THE TASK FORCE ON SUGGESTED STATE REGULATIONS FOR CONTROL OF RADIATION

(Presented by Marshall Little, Bureau of Radiological Health, FDA)

Introduction

The latest revision of the Ionizing Radiation Category of the Suggested State Regulations for Control of Radiation (SSRCR) was completed in the fall of 1974 and sent to the States by the Chairman of the Conference of Radiation Control Program Directors in December 1974. A Notice of Avalability on that revision was published in the FEDERAL REGISTER on July 15, 1975 in order to indicate its availability and to invite comments from interested persons and groups for use in future revisions. Comments were received on all parts of the 1974 SSRCR and provided to the appropriate working group members for their consideration in revision of their part.

Current Revision

The present plan is to work on revision of the SSRCR on a continuing basis to assure that it is maintained consistent with recent amendments to Federal radiation control regulations; to consider current voluntary guidance and recommend to be responsive to suggestions and comments received; and to resolve matters deferred from the previous revision. "Guidelines on Review and Revision of the SSRCR" were provided to all working group members setting forth criteria and methods for revision of their part, including the need for development of a rationale report to document the reasons for the amendments to that part and a report of the analysis completed and action taken on comments received. Due to the extent of work required on some parts and unexpected problems, it has not been possible for all working groups to maintain the schedule of target dates set up for completion of their part of the project.

The 1974 SSRCR was a cooperative project of the Conference of Radiation Control Program Directors (CRCPD), the Bureau of Radiological Health (BRH), and the Nuclear Regulatory Commission (NRC). For the current revision of the SSPCR, agency involvement has been expanded by inclusion as members of selected working groups or invitation to participate in working group meetings. On those parts undergoing extensive revision, the review process has been broadened to include approximately 200 different groups or agencies including State and local radiation control agencies; Federal agencies with interest or responsibility in radiation control; standard-setting groups; professional organizations; industrial associations; international organizations, when appropriate; and members of other SSRCR working groups.

Status of Parts

The Part C Working Group on Licensing of Radioactive Material met early in the year to revise Part C and prepare a rationale report on the changes based on comments received and amendments to Federal regulations. The revised draft and rationale was forwarded in April 1976 to all CRCPD and Federal agency representatives to the working group for final review. Part C was revised to reflect amendments to NRC regulations in Title 10 Code of Federal Regulations Part 31 (General Licenses for Byproduct Material); Part 32 (Specific Licenses to Manufacture, Distribute, or Import Certain Items Containing Byproduct Material);

and Part 35 (Human Uses of Byproduct Material). This included incorporation of NRC extended group medical licensing regulations into Part C. Accelerator-produced materials were added to Schedule C on Groups of Medical Uses of Radioactive Material. Also, the concept of "Licensing State" was added to the revised draft of Part C to recognize licensure of naturally occurring and accelerator-produced radioactive material (NARM) in addition to the licensure of byproduct, source, and special nuclear material. The Part C Working Group has worked closely on this with the CRCPD Task Force No. 1 on Evaluation and Distribution of Radioactive Sources and Devices Not Manufactured Under the Atomic Energy Act. Members of the Part C Working Group are: A. J. Hazle, Chariman, Colorado; James A. Blackburn, Illinois; Allan Tapert, BRH; and John McGrath, NRC.

Part E on Radiation Safety Requirements for Industrial Radiographic Operations was not revised for the 1974 SSRCR, but was delayed to incorporate final provisions of the Federal Cabined X-Ray Systems Standard. The Part E Working Group met in June 1975 and prepared a revised draft and rationale. The Part E draft and rationale also was distributed for review to over 200 groups including State and Federal agencies, professional organizations, standard-setting groups, and industrial associations. The Part E Working Group met again in December to analyze the comments received and revise the drafts as necessary. An analysis of comments document was prepared along with the revised Part E and rationale report to indicate action taken on each of the comments received. A new section on "Records Required at Temporary Job Sites" was added to Part E in order for the Agency to effectively inspect and evaluate the radiographic operation. The section on Personnel Monitoring Control was changed to conform to NRC amendments to 10 CFR 34.33 (39 FR 36601, October 11, 1974). The change would allow use of either TLD or film badges by industrial radiographers and their assistants, and would require that direct-reading pocket dosimeters be used instead of indirect-reading pocket chambers. The section on enclosed radiography was revised to include the Cabinet X-Ray Systems Standard (21 CFR 1020.40). Requirements were added that certified cabinet x-ray systems be maintained in conformance with provisions of 21 CFR 1020.40 and that the registrant conduct on evaluation of the system at least annually to determine conformance with 21 CFR 1020.40. Matters for future consideration to Part E include the addition of other industrial uses of radiation sources (e.g., industrial gauges and fluoroscopy) and provisions regulating the use of radiation sources in oil and gas well logging operations. Members of the Part E Working Group are: B. Jim Porter, Chairman, Louisiana; Joseph J. Franaszek, California; Edgar Bailey, Texas; John Taschner, BRH; and John McGrath, NRC.

The diagnostic x-ray portions of Part F (X Rays in the Healing Arts) were completely revised in the 1974 SSRCR. In addition to other changes, Part F of the 1974 SSRCR contained appropriate provisions of the Federal diagnostic x-ray standard so States could use to meet requirements of Sec. 360 F of the Public Health Service Act, as added by Public Law 90-602. In this latest revision of Part F, major attention has been devoted to the x-ray therapy sections (Sec. F.8 and Sec. F.(). In preparation for work on this part, a letter was sent to all conference members in May 1975 by the Chairwoman of Part F requesting suggestions on revision of the teherapy sections. The Part F Working Group met in September and November 1975 to review suggestions received and prepare revised drafts of Sec. F.8 and Sec. F.9 and rationale. The new therapy section drafts and rationale then were distributed for extensive review to over 200 groups including State and Federal agencies professional organizations, standard-setting groups, and industrial associations. The Part F Working Group met again in January 1976 to revise the therapy section drafts and rationale based on comments received. Two-hour telephone conferences have been held among the members of the Part F Working Group and resource persons since January in an effort to complete work on the therapy sections and the rationale and analysis of comments documents. Comments received on the diagostic X-ray portion of the

1974 SSRCR are also being reviewed and an analysis of comments document prepared. Due to the heavy work load on the therapy sections and handling comments on the diagnostic x-ray portion of Part F, the veterinary x-ray section (Sec. F.10) will be deferred for the next revision of the SSRCR. Members of the Part F Working Group are: Alice Dolezal, Chariwoman, Minnesota; Coleman Smith, Oklahoma; Robert England, California; BRH; Paul Leggett, BRH; and James Martin, EPA.

On Part G (Sealed Sources in the Healing Arts), some comments were received in response to the Notice of Availability regarding the 1974 SSRCR published in the FEDERAL REGISTER. In addition, a memorandum letter was sent to local, State, and Federal agencies requesting their review and comments on the October 1974 draft of Part G and completion of a questionnaire. Forty-three replies to the memorandum letter were received. Based on comments received, a revised draft of Part G is being prepared. Members of the Part G Working Group are: Dale McHard, Chairman, Oklahoma; Donald Thompson, BRH; and John McGrath, NRC.

The Part H Working Group on analytical x-ray equipment met earlier this year to review comments received on Part H in response to the Notice of Availability on the 1974 SSRCR published in the FEDERAL REGISTER. Based on their analyses of comments, suggested changes were developed for the revised draft of Partr H and rationale. Members of the Part H Working Group are: William Aaroe, Chairmen, Philadelphia; Donald McDonald, Pennsylvania; and Thomas Moore, BRH.

The Chairman of the Part J Working Group on "Notices, Instructions and Reports to Workers; Inspections" sent a letter to all conference members requesting comments and suggestions on needed revisions to Part J. Based on a review of the comments and suggestions received, amendments to Part J were developed. A draft of Part J and a Rationale Report was completed by December 1975 to meet the target date, and copies forwarded to the participating groups for their concurrence. Members of the Part J Working Group are: Philip Brunner, Chairman, Illinois; Charles Froom, BRH; John McGrath, NRC; and Luis Garcia, EPA.

Part A on General Provisions; Part B on Registration; Part D on Standards for Protection; and Part I on Particle Accelerators will include only minor amendments in this revision. Some definitions needed for other parts of the SSRCR will be added to Part A. Part B was extensively revised in 1974 and has received minimal comments. The Part D Working Group met in October 1975 to review comments and suggestions received, but changes in this revision will be limited to the addition of amendments to NRC regulations. The members of these four working groups are as follows:

Part A - Gene Christianson, Chairman, North Dakota; John Munzer, BRH; John McGrath, NRC; and DeVaughn Nelson, EPA.

Part B - Donald E. Van Farowe, Chairman, Michigan; Lois Miller, ROS/EDRO, FDA.

Part D - Gerald W. Allen, Chairman, Kansas; Gail Schmidt, BRH; John McGrath, NRC; and DeVaughn Nelson, EPA.

Part I - Thomas M. Gerusky, Chairman, Pennsylvania; and Robert Jacobs, BRH.

Proposed new parts are being considered for inclusion in the Ionizing Radiation Category of the Suggested State Regulations for Control of Radiation. They are Part K on radiopharmacies and Part L on nuclear medicine. A meeting of selected persons was held in Seattle to discuss plans for development of these parts. David Lacker, Texas, was selected as the Chairman of Part K and Marshall Parrott, Oregon, was selected as the Chairman of Part L.

In the Nonionizing Radiation Category, the working group on the Suggested State Regulations for Lasers (SSRL) will continue work to complete their final draft, rationale report, and analysis of comments in the next few months. CRCPD members of the Working Group on the SSRL are Jack C. Rogers, Chairman; Francis J. Bradley, New York State Department of Labor; and Joseph Thiel, Texas.

TASK FORCE REPORT ON NATURAL RADIOACTIVITY CONTAMINATION

Ulray Clark

(Robert C. Will, Chairman speaking for Mr. Clark)

The Task Force on Natural Radioactivity Contamination was one of those groups that suffered from budgetary problems this year. Ray Clark discussed this task force with us last evening; he does not have a report available for presentation. He has had to forego the chairmanship in favor of Hal Bodenger of Louisiana who, also, could not attend the Conference.

With this in mind, we have nothing further to report at this time. There will be information forthcoming on this particular group in the near future. I think my own comment is that these people are beginning to reveal some problems that we did not know we had, and they are pretty big ones.

TASK FORCE REPORT ON RADIOACTIVE WASTE MANAGEMENT

Heyward G. Shealy, Chairman

The Task Force on Radioactive Waste Management was continued as a three-member staffing committee. The purpose for continuing the Task Force on a limited basis was to serve as a liaison function to provide a forum where State and Federal agencies could discuss matters of mutual concern. Also, such a forum would meet the need of industry to have a single contact with Government away from management matters.

During the past conference year, a number of events have taken place with respect to commercial low-level waste burial facilities.

(1) Issuance of a U.S. General Accounting Office Report entitled "Improvements Needed in the Land Disposal of Radioactive Wastes: A Problem of Centuries."

(2) Congressional hearings on low-level radioactive waste disposal by the Subcommittee on Conservation, Energy, and Natural Resources of the House Government Operations Committee.

(3) Shut-down of two of the six commercial low-level radioactive waste disposal sites.

(4) The creation of an informal working group by NRC on low-level waste burial. This group will encompass Federal agencies and States that have a mutual interest.

(5) Issuance of U.S. Environmental Protection Agency report entitled, "Preliminary Data on the Occurrence of Transuranium Nuclides in the Environment at the Radioactive Waste Burial Site at Platts, Kentucky, February 1976."

The Task Force on Radioactive Waste Management was created as a result of recommendations made by Workshop No. 5 in 1972 at the New Orleans National Conference meeting. Subsequent task force meetings were held each year. Task Force reports were submitted to the Conference during 1973, 1974, and 1975. Problems and areas of concern - sites, States, and burial facilities - were documented.

The basic recommendations and observations made by the task force have been reemphasized in a U.S. General Accounting Office report entitled, "Improvements Needed in the Land Disposal of Radioactive Waste: A Problem of Centuries." Hearings on land disposal of low-level radioactive wastes began during February 1976. The Congressional hearings were called by the Subcommittee on Conservation, Energy, and Natural Resources of the House Government Operations Committee. Following the issuance of the U.S. General Accounting Office report, testimony was presented by five Federal agencies and one burial site company. The hearings were subsequently closed on March 12, 1976. The hearings were reopened on April 6, 1976, for input from sites, States, and commercial low-level burial facilities. The States of Illinois, Nevada, and South Carolina participated in the hearings. It was not until after a special effort was made by the States that the hearings were reopened for a limited period of time for State input.

During the past several years, burial site States have been barraged with audits, questionnaires, reviews, requests for records, report writing by Federal agencies, hearings, inquiries, and so forth. Situations, such as burial and different burial sites have been defined and redefined by separate entities.

The Task Force feels that the increased radioactive waste disposal activities of the past year warrant a need for additional attention by the Congress. We recommend that the Task Force be expanded to include a representative from each State having a burial facility. Only States with commercial burial facilities should be represented. The Federal resource persons should be expanded to include a representative from ERDA and the U.S. Geological Survey.

It is recommended that the Task Force on Radioactive Waste Management be continued and expanded by the Conference in an effort to work with Federal agencies in seeking answers and solutions to problems encountered by sites and States.

REPORT OF THE TASK FORCE ON BONDING and PERPETUAL CARE OF NUCLEAR LICENSED ACTIVITIES

Al Hazle, Chairman - Colorado
Bob Wolle - Tennessee
Aubrey Godwin - Alabama
Shelley Schwartz - NRC
Wayne Kerr - NRC
Paul Lohaus - NRC
Harry Calley - EPA

The charge to this Task Force is: (1) To evaluate the needs for and find mechanisms for initiating bonding; to coordinate and, where necessary, recommend Federal legislation to achieve this, (2) To investigate the availability of other viable supplements to bonding.

Several States have taken action in regard to this topic. Alabama has introduced legislation to allow bonding; however, it died on the floor because of other priorities. Arkansas and North Carolina have bonding legislation as of 1975. New Hampshire also acted to acquire the authorization to require bonding; however, nothing developed as a result of their action.

EPA has stated that they have no direct authority either in the establishment or implementation of NRC licensing requirements; however, they do share the concern of the Conference in this matter and will continue to work with the Conference and NRC in studying this problem and developing feasible solutions. From a Federal standpoint, NRC has the lead role, and any EPA involvement would be limited to identification of suitable mechanisms.

The Nuclear Regulatory Commission has stated that the use of bonding and trust funds to assure that sufficient funds are available to decontaminate or decommission a licensed activity in the event of licensee default is a question that has arisen a number of times over the past several years. According to NRC, it is difficult to justify the wide-scale bonding, as outlined in the Task Force Report, on the basis of experience. The Nuclear Regulatory Commission is now considering how best to provide for decommissioning in the event of licensee default for uranium mill licensees, major processors, former AEC license facilities (10 CFR 50) and other specific licensees that are identified by the Task Force. This is a major policy question that would require careful consideration by the Commission, and the use of bonding and trust funds may be one of the alternatives which should be considered.

The Task Force met December 11 & 12, 1975, in Nashville, Tennessee, and February 12 & 13, 1976, in Denver, Colorado. A telephone conference was held April 5, 1976 to finalize this year's effort.

The previous submission to the Conference by this Task Force was reaffirmed, and stated that it was, in fact, a very viable document.

Some items of discussion were brought forward: Viable alternatives: (1) Bonding -- This would be used for immediate needs covering essentially a 1-year period, (2) Trust Funds -- These would be for long-term use, primarily for perpetual care.

Alternatives that were reviewed, but felt not viable are : (1) Insurance, for third-party protection; (2) A national indemnity fund provided by States; (3) Financial qualification review determining periodic solvency; and, lastly, (4) Lien laws which are superior and prior to all other liens and would carry a clause to that effect.

Insurance - The Task Force considered nuclear liability insurance as an alternative. After careful review and much discussion, the Task Force cannot recommend this alternative. There was agreement that insurance was a third-party protector. Discussion brought out that insurance will tend to prevent a large liability suit, on collection, forcing a company into bankruptcy. Further discussion also revealed a possible use of insurance to remove some contaminating sources. This feature would only occur after damage to a third party, and only if you can show the insurance company that it would be to their advantage to remove contamination. We feel that an agency may wish to explore insurance on a case-by-case basis.

The body of the report submitted last year was reviewed in detail and revised in accordance with the current findings of the Task Force.

It was felt that the Western Interstate Nuclear Board study on uranium mills for bonding and perpetual care, which should be available later this year, would be a definite adjunct to the deliberations of this Task Force. We recommend referral of the recommendations on amendment of Part C and proposal for legislation to the Task Force No. 6 on Part C of the Suggested State Rules and Regulations for Radiation Control.

(The following is the complete Task Force Report.)

TASK FORCE REPORT ON BONDING AND PERPETUAL CARE OF NUCLEAR LICENSED ACTIVITIES
April 5, 1976

PREFACE

There is a need for States and other territorial governments to protect themselves from financial burdening should a licensed nuclear facility not be able to decommission its activities upon termination of a license. This has occurred in several States already, and several States have taken action to acquire the necessary legislation to allow the authorization of bonding requirements on certain licensees. WHILE THIS MAY PROTECT THE STATES AND OTHER GOVERNMENT AGENCIES FROM ENORMOUS FINANCIAL LOSS, IT SHOULD BE REALIZED THAT THIS MODE OF PROTECTION IS NO SUBSTITUTE FOR A VIABLE RADIATION PROTECTION PROGRAM.

Bonding is anticipated for use in the immediate decommissioning of the facility covering approximately a one year period. The trust funds or escrow accounts should be provided for use in long-term or perpetual care and maintenance programs. Insurance would be an alternative for third party protection should that be deemed necessary. Other alternatives were considered, however, they were not generally considered viable.

It was the feeling of the Task Force members that such financial protection is not deemed necessary in the majority of cases, and should be reviewed by each State as to the applicability of its circumstances and those of its licensees.

The appendices of this report include suggested legislation for licensee bonding and perpetual care trust funds and, also, changes to the suggested State regulations allowing the authorization of such bonding and perpetual care funds.

INTRODUCTION

The Task Force on "Bonding and Perpetual Care of Licensed Nuclear Activities" was established by the Executive Committee of the National Conference of Radiation Control Program Directors during June, 1974, in joint sponsorship with the Nuclear Regulatory Commission (NRC) and the Environmental Protection Agency (EPA), to investigate options available to States to assure licensee financial responsibility in the event of default. This Task Force is an outgrowth and extension of previous Conference deliberations on radioactive waste management, and bonding and perpetual care requirements for shallow land burial sites. Because similar considerations relating to bonding requirements exist for all types of nuclear activities, the specific charge of the Task Force was to examine, in detail, the requirements for establishing bonding and perpetual care programs for all types of licensed nuclear activities, and to report the findings of the Task Force as guidelines to assist States in program development. Therefore, this report addresses only the options of bonding and perpetual care and is an update of the January 20, 1975 Task Force Report. Other mechanisms of financial responsibility such as a national indemnity fund, taxation, insurance, and financial qualifications were considered.

A previous examination of the status of bonding programs as they relate to licensed nuclear activities (excluding waste burial licensees) indicates only one State, New York, had instituted such a program, however, several States expressed concern in this area and are interested in the results and recommendations of the Task Force. During 1975, North Carolina and Arkansas passed bonding legislation. This increasing concern is attributable primarily to the possibility that a State might have to assume the responsibility for restoring a site where a licensed nuclear activity was conducted, to a radiologically safe condition and/or maintaining the site in perpetuity. Commensurate with the technological advances and proliferation of the nuclear industry, the complexity of the restoration process of any licensed activity will, in all probability, require financial resources not available to the State. Since the public health and safety must not be compromised, it becomes necessary for the State to initiate actions to insure that its public responsibilities are met. While other concepts of assuring financial responsibility as a prerequisite for licensure are available and used, (e.g., the financial responsibility concept used by the NRC) it was concluded that the bonding and trust fund concept would satisfy many of the situations that an individual State may encounter and is, in the majority of cases, the method of choice.

The objective of the Task Force effort was to assemble into a single document the guidance necessary for State and Federal officials to develop bonding and perpetual care programs. Specific work topics were identified by the Task Force and in formulating the guidance, the approach taken was as follows:

- to determine, in general classes, those licensed activities which may require consideration for bonding and/or perpetual care
- to identify the legislative authority necessary to establish bonding and perpetual care programs
- to develop monetory ranges of performance bonds and perpetual care trust funds
- to identify administrative areas to be considered by the State in developing, implementing and maintaining bonding and perpetual care programs.

Ensuing portions of this report discuss each identified topic in detail, and in some cases, (e.g., legislative requirements) offer several alternatives and examples that may be considered. While attempting to suggest monetary ranges for performance bonds and trust funds, the Task Force found it difficult to establish an exact cost estimate for any given class because of the variance of basic costs, as well as the differing restoration/maintenance requirements peculiar to the class. Wide monetary ranges are presented and are considered by the Task Force to be representative of minimum and maximum costs that may be encountered; however, each State must, using the identified parameters, evaluate the financial requirements of a given class by an individual cost analysis.

Finally, the Task Force has identified potential issues which should be considered prior to the adoption and implementation of any bonding or perpetual care program. Primarily, the issues relate to the following:

- licensing and regulatory jurisdiction over decommissioned facilities originally licensed by the NRC
- difficulties that may be encountered by States if the NRC fails to adopt similar programs
- reciprocal recognition of bonds between States and between States and the NRC
- individual variability between States

- restricted availability of large dollar-amount bonds due to the collateral requirements.

Part IV, Recommendations, attempts to resolve these issues and also contains recommendations of the Task Force for a systematic approach to bonding/perpetual care programs.

The Western Interstate Nuclear Board is preparing a report of a similar nature on uranium mills and that report should provide additional information on this subject.

PART I PROBLEM DEFINITION

To investigate bonding and trust funds as a mechanism available to the State or Federal agency having regulatory jurisdiction over the activities of certain classes of users of radioactive materials to assure that sufficient funds will be available to decontaiminate or decommission a licensed activity. The user classes identified are:

1. major processors of radioactive material (not including special nuclear materials sufficient to form a critical mass)

2. waste handling licensees

3. ore refineries - mills

4. former NRC licensed facilities which utilized special nuclear materials sufficient to form a critical mass

5. other specific licensees.

The establishment of a financial responsibility program cannot be substituted for a sound, well-executed regulatory program, but employed only as a contingency in the event of licensee default. The Task Force has not endorsed the need for bonding of all licensees but if deemed necessary, the suggested legislation provides the mechanisms for such a program. Bonding and trust fund requirements should be instituted to assure the availability of money needed for the closing of nuclear activities and/or bonding the performance of a licensee relative to the protection of the public health and safety. Bonds would provide immediate, short-term financial resources to control and/or eliminate the radiological hazard; while trust funds would provide financial resources for long-term maintenance and surveillance costs if complete removal of the hazard is not accomplished.

For purposes of this report, the term "bond" means a contractual obligation in writing binding the obligor (licensee) to observe the provisions of the Laws, Rules and Regulations, Special Conditions, and Orders governing the issuance of the license, and in failutre to follow such, to pay a sum of money to the obligee (agency) and permit the obligee or its designee to enter the property of the obligor for purposes of decontaimination, with the stipulation to the effect that on performance of a certain condition (i.e., satisfactory decontamination by the obligor) the obligation shall be void. Used in this context, an acceptable bond may be any of the following:

1. a bond issued by a fidelity or surety company, if available

2. a personal bond secured by collateral

3. a "letter of credit" issued by a recognized financial institution

4. a cash bond posted by the licensee.

Bonds of this type are usually renewed on an annual basis and contain a short-term (30 days) cancellation clause by the surety which may require immediate action by the Agency.

In the context of this report, a "trust fund" means a legally established fund or aggregate of assets dedicated by the Trustor for the specified purpose of underwriting all costs of maintenance and surveillance of sites which pose radiation hazards or require continuing care; and which the beneficiary can spend under terms of the trust agreement only to effect the specified purposes.

I. MAJOR PROCESSORS

A major processor is considered to be a user processing, handling, or manufacturing radioactive materials exceeding Type A quantities as unsealed sources or material or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, radiographers or small industrial programs. Type A and B quantities are defined in 10 CFR 71.4.

A. NEED

A radioactive material user of this size usually will initially have an adequate financial base and can sustain significant expenses in decontaiminating equipment or facilities and providing for the annual maintenance and surveillance of the site as required. In time, the company's financial resources tend to become limited if it cannot maintain its market position. In the event of a contaminating incident at the plant, the company may no longer have the financial resources to adequately correct the situation. The bond would provide funds to accomplish that task.

B. FACTORS TO CONSIDER IN SETTING THE AMOUNT OF A BOND

Setting the amount of the bond involves a complex evaluation of the licensee's activities being bonded. Factors to be considered are:

1. the amount, isotope, and chemical form of radioactive materials involved

2. facility structural factors, for example

   a. types of ventilation
   b. isolation capability
   c. double containment and building design
   d. above or below ground operations
   e. fencing or other access control

3. environmental factors, for example

   a. water table
   b. meteorology
   c. migration rate (soil)
   d. surrounding water and land use
   e. access to facilities

4. costs of decontaminating rooms, equipment, etc.

5. costs of soil removal and disposal

6. costs of debris removal and disposal, and

7. annual maintenance and monitoring costs.

C. ESTIMATED COST RANGE: $1000,000 to $5,000,000

After reviewing a proposed decommissioning of a major processor and discussing the factors to be considered in estimating restoration costs, the Task Force selected the estimated range as being representative of costs that may be incurred. Appendix A contains a summary of the estimate of a recent decommissioning of a major processor. The upper bound of the estimate includes complete removal.

II. WASTE HANDLING LICENSEES

Waste handling licensees include organizations which hold radioactive wastes for later disposal and those which actually dispose of the wastes. Storage or holding of wastes generated solely by the storing organization would not be included. Those licensees which process the wastes prior to disposal should be considered major processors if the quantities of radioactive material which they are authorized to possess meet the amounts described for that class.

A. NEED

The need for the bonding of waste handling license activities has been discussed in a previously developed statement by the National Conference of Radiation Control Program Directors and is Appendix B to this report. For those sites which serve as a temporary storage for wastes, the need as given for major processors above is appropriate. In addition, one should be aware that generally these companies do not have the equipment or mortgate base available should funds be needed.

B. FACTORS TO CONSIDER IN SETTING THE AMOUNT OF A BOND

Setting the amount of the bond for a waste burial site has been previously developed by the National Conference of Radiation Control Program Directors and is also included in Appendix B to this report. it should be stressed that the bond established for this type of licensee is for basically three things:

1. burial of any wastes not buried by the operator

2. payment of any monies due the perpetual care fund, and

3. preparation of the site for a new operator or for decommissioning.

Setting the amount of the bond for other waste handling licensees generally follows the factors considered for major processors. One should recognize that in many cases these licensees do nothing but handle Department of Transportation approved packages, thereby reducing the hazard potential.

C. ESTIMATED COST RANGE: $50,000 to $500,000

Included in estimating these amounts are the decommissioning costs, funds due the perpetual care trust fund at the time of default or forfeiture and the maintenance and monitoring of the site for at least one year to permit possible site reactivation, if desirable. Perpetual care trust fund inclusion plays an important role in arriving at such a figure. A "point-of-no-return" would be identified at which time complete removal could no longer be economically considered in light of the health benefits involved.

III. ORE REFINERIES - MILLS

Ore refineries include all processors of a radioactive material ore. The product of this processing should not exceed the low specific activity definition given in 10 CFR 71.4(g). The waste product of the processing is usually radioactive "tails." Those processors handling radioactive materials concentrations above the low specific activity levels are considered major processors if the quantities possessed otherwise meet the amounts described for that class.

A. NEED

The need for bonding is best described by the need for continual control of the "tailing pond," or "tailing pile," or other retention system. The company operating the facility is subject to the same adverse financial conditions as described for major processors. In addition, the "tails" are likely to be considered disposed of and therefore may require extemely long term care.

B. FACTORS TO CONSIDER IN SETTING THE AMOUNT OF A BOND

The factors used in setting the amount of a bond for a major processor also apply to this class; however, certain modifying factors should be considered. These are:

1. Any contamination is low specific activity; therefore, decontamination of facilities and equipment is easier and cheaper.

2. The long term care requirements of the "tailing pond," "tailing pile" or other retention system, may require the establishment of a perpetual care fund. Appendix B discusses the establishment of a perpetual care fund and this Task Force recommends its consideration.

C. ESTIMATED COST RANGE: $500,000 to $5,000,000

The cost range is for licensees with tailing piles and without need for relocation of the pile. A major consideration is the amount required for stabilization of the pile in connection with decommissioning of the facility. If a mill tailings pile, or other waste retention system, is not associated with the authorized use, appropriate downward adjustments of these figures would be required.

IV. FORMER NRC LICENSED FACILITIES

These facilities include all nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, and critical mass experimental facilities.

A. NEED

Former NRC licensed facilities may be divided into two classes: (a) those with large inventories of mixed fission products and some transuranics; and (b) those with no transuranics and small inventories of mixed fission products. In all cases, long half-life materials are involved, and therefore the contamination must be removed or long term monitoring and perpetual care instituted. Otherwise, the need is the same as for a major processor.

B. FACTORS TO BE CONSIDERED IN SETTING THE AMOUNT OF A BOND

The factors to be considered in setting the amount of bond vary according to facility type. Generally, the considerations of a major processor apply, but additional factors should be taken into account for each type of production or utilization facility. These are:

1. Nuclear Reactors - The current NRC regulations provide for a detailed review of an applicant's financial resources to assure that the applicant can safely operate a nuclear power plant. Additionally, while in operation, the nuclear power plant represents a major asset to the operator; however, after the plant is decommissioned or shut down, it becomes a liability. It appears that the former nuclear reactor licensee will be under strong economic incentive to transfer title to another entity and thereby reduce the long term liability. It is recommended that any person holding an NRC "possession only" license for a decommissioned nuclear reactor be required, at the very least, to post a bond sufficient to provide a perpetual care fund covering the monitoring and maintenance costs for the facility.

2. Nuclear Fuel Reprocessing Plants - The considerations for this type of facility are the same as for a nuclear reactor.

3. Uranium Enrichment Plants - The considerations for this type of facility are the same as for major processors.

4. Critical Experiments Facilities - Those in low power range (< 10 watts) have low fission product inventories and have the same considerations as major processors. Those in the high power range (> 10 watts) should be considered, for bonding purposes, similar to nuclear reactors.

C. ESTIMATED COST RANGE: $50,000 to $500,000

1. Nuclear Reactors - $50,000 to $500,000

The estimated bonding costs for nuclear reactors depend on which of the four alternatives provided in the Regulatory Guide 1.86 "Termination of Operating Licenses for Nuclear Reacors" are used, the size of the reactor and the decontamination problems associated. Residual radiation levels on sites for unrestricted use should be as low as practicable but in any case far below those specified in Table 1 of the Guide. The estimated cost range does not include those decommissioning costs associated with termination of the NRC operating license but only includes those costs which may be incurred to provide annual maintenance. The cost of decommissioning a two-reactor facility has been estimated at approximately $2,000,000, with a $100,000 annual maintenance cost. A complete removal of all radioactive material has been estimated at $75,000,000

2. Other Former NRC Licensed Facilities - $50,000 to $500,000

3. Critical Experimental Facilities - $10,000 to $100,000

V. OTHER SPECIFIC LICENSES

A. NEED

Most of the users of radioactive material present a low potential for a major problem. For example, if a user of a gauge containing radioactive material declares bankruptcy, shipping the gauge to a licensed recipient is all that is required. Similarly, small research programs, nuclear medicine programs, industrial radiography, etc. each represent a fairly low cost decontamination problem. One should note that many programs start in this class and grow into another.

B. ESTIMATED COST RANGE: $1,000 (10,000) to $500,000

Except for those licensees exempt or excluded from the recommended bonding requirements, an appropriate "across the board" (one amount for the entire class of licensees) application of a bond amount would be between $1,000 and $10,000 as a minimum. A normal maximum for this class would approximate $500,000. Complete removal of radioactive material is anticipated.

In providing guidance for perpetual care trust funds, the Task Force recommends that for only two cases -- waste handling licensees and source material ore milling operations -- should perpetual care funding be initially provided. Perpetual care funding may also be required for formerly AEC or NRC licensed facilities. All other sites would be expected to be decontaminated to a level as low a practicable to protect the public health and safety. This policy would preclude proliferation of perpetual sites throughout the nation. The interest on the amount required to be maintained in the trust fund should provide an annual amount equal to the anticipated costs of perpetual care. Anticipated costs of perpetual care for both waste handling facility and ore refinery sites would range between $50,000 to $250,000 per year. A trust fund principal of $3,000,000 will yield approximately $150,000 in interest annually, according to the 1974 National Conference Workshop #3 Report. The Report of Workship #3 contains information as to the items of concern in providing perpetual care.

Bonding provides for the infrequent case in which a licensee is unwilling or unable to appropriately provide for decommissioning and the monies due to the perpetual care fund for the site. Perpetual care trust funds allow for the continuation of appropriate management of the site into the foreseeable future. It should be noted that bonding and perpetual care trust fund provisions do not provide for third party protection. While the Task Force was of the opinion that the licensing agency was under no obligation to require such insurance, it may be advisable to identify if licensees have provided for this matter.

PART II AUTHORITY

The purpose of this part is to discuss (1) the necessary legislative authority for requiring licensees to assure their financial responsibility through the posting of bonds and establishment of perpetual care trust funds; and (2) the requisites of performance bonds and trust funds. The Task Force is aware that some Agreement States have already determined that specified legislation to authorize bonding and trust funds of their licensees is not required, since their legal counsels have determined that the existing legislation establishing their agency provides sufficient authority for establishment of these requirements. However, the Task Force believes that most States will require an amendment to existing legislation in order to specifically grant the State the authority to require bonds and trust funds. Counsel in at least one State has stated that although existing law does not prohibit the imposition of bonds, the State would be in a stronger position if the legislation specifically granted the authority for the requirement of bonds.

Each State should investigate with its own legal counsel which of the two following approaches is appropriate for requiring bonds and establishing perpetual care funding within the State.

I. STATES WHERE EXISTING LEGISLATION IS DEEMED ADEQUATE

For those States where legal counsel deems that the existing legislation provides sufficient statutory authority for the requirements of bonds and establishing perpetual care funding, the following criteria should be met :

A. The legislation should provide sufficient authority to establish the bonding and perpetual care fund requirement.

B. The authority to establish bonds should be broad enough to require bonds of adequate types and amounts.

C. The authority to establish perpetual care funding should be broad enough to cover the amounts needed for long term maintenance and surveillance of the site.

D. The legislation should specify where the proceeds of forfeited bonds are to be deposited and how they can be used.

E. The legislation should state any exclusions or exemptions from bonding and perpetual care requirements which may be deemed appropriate (e.g., State and local agencies) and should have a provision that additional exemptions by types of licensees may be provided by the State regulatory agency.

Where the State deems that the existing legislation is appropriate and meets the criteria as stated above, its rules and regulations implementing the statutory authority should be amended and, as a minimum, provide for the following:

A. A definition of what constitutes an acceptable bond (this may be defined within the state statute).

B. An effective date of the rule or regulation allowing at least a 90-day period for implementation.

C. A specific description of how the forfeited funds may be used; e.g., cleanup of contaminated facilities, etc.

D. A mechanism for administering the bonding and perpetual care requirements for existing State licensees.

E. A requirement that the bond be issued and in the possession of the State regulatory authority at the time the license is issued.

F. A requirement that the perpetual care fund be established prior to the time the license is issued.

G. A requirement for the provision of adequate bonding by range of dollar amount and a statement that all exemptions may be based on possession limit, form or other category deemed appropriate.

Appendix C "Proposed Changes to the Suggested State Regulations" contains an example of the language necessary to amend Section C.25 to include the above requirements.

II. STATES WHERE IT IS DEEMED THAT AMENDMENT OF EXISTING STATUTES IS NECESSARY TO AUTHORIZE IMPOSITION OF BONDING AND PERPETUAL CARE FUNDING REQUIREMENTS FOR LICENSEES

All of the criteria for legislation and provisions that should be incorporated in the State rules and regulations, as discussed in the previous section, should be followed in conjunction with the enactment of amendment of existing State statutes to authorize bonding. Suggested language for such amendatory legislation is contained in Appendix D "Suggested Legislation for Licensee Bonding and Perpetual Care Trust Funds."

III. OTHER CONSIDERATIONS

In addition to the legislative authority necessary to establish bonds and trust funds, each State regulatory agency should determine clearly what constitutes a legal bond or trust fund within the State. In the case of establishment of trust funds, the ownership of the land must be clearly defined. It is the Task Force's opinion that although bonds should be required of most specific licensees, trust funds for perpetual care are only necessary for waste handling licensees and ore refinery activities where tailings piles are generated. However, it was also considered that trust funds for perpetual care should probably be established for any former NRC licensed facility when it is decommissioned and when there is a likelihood that it will become a permanent disposal site as opposed to total dismantling of the facility or decontamination. Most States already have requirements for trust funds for waste handling sites, but these are all located on State owned property. In the case of ore refinery sites and former NRC licensed facilities, they are normally located on private property and thus the problem of ownership of the land must be clearly resolved.

PART III ADMINISTRATIVE

It should be recognized by the agency that implementation of a bonding/perpetual care program is no small undertaking either for the licensee or the agency. It is most important that the bond be in effect prior to issuance of the license, which is basic to the concept of any resultant legal procedure and is the only way adequate protection can be provided. Therefore, it should be a condition of issuing all new licenses that the bond be in effect prior to issuance of the license. Assuming legislation or other legal authority authorizes the establishment of bonding/perpetual care programs, administrative procedures must be developed and provided to implement the program. Because bonds will frequently be a very significant cost item to some licensees, bonding requirements should be clearly delineated in the regulations governing the issuance of licenses by the agency.

Imposition of a bond upon all existing licensees should be accomplished by requiring all existing licensees to obtain a suitable bond as a condition of the license within a specified period ot time or making a bond a condition of licensure at the time of renewal. In either case, adequate warning and necessary information as to the specific requirements of the bond should be provided to all licensees. Each licensee should be notified in writing as to the range of bond amount required. The time permitted should recognize the economic, legal, and administrative impact upon the licensee and the agency. Consideration should be made of the establishment of a priority system for administering the requirements of existing licensees. The letter should also provide information as to the availability of such bonds within the agency's jurisdictional area and should be clear of any implication of "conflict of interest."

It should be reemphasized that considerable staff time will be required of the Agency to implement this facet of its program with a lesser requirement for its maintenance. It is estimated that an agency having 500 existing licenses and which imposed a standard bond amount upon all such licenses, would require 1.5 to 2.0 man-years of technical staff for implementation and require 0.3 man-years effort for maintenance. It would also require 0.5 man-years clerical and secretarial staff time. In addition to staff time, all other costs for agencies such as legal services should be considered if there is not a legal staff available to the agency.

Adequate written guidelines for staff use and implementation of the program should be provided. These should include procedures for the following:

1. Basic administrative processing of the bonding requirements in concert with existing administrative procedures of the agency and in accordance with a possible priority system.

2. Basic legal processing in accordance with laws governing such legal instruments.

3. Specific guidelines to be used in determining the amount of the bond required for each specific license.

4. Periodic review of bonding requirement as a normal license review and/or amendment procedure.

5. Periodic review at the expiration of the bond or license.

6. Provision for an adjustment of bond amount for inflation.

7. Implement a safe depository for the bonds.

8. Provision of written procedures to be implemented in the event of failure to perform adequately by the licensee requiring forfeiture of the bond.

9. Provision for the transfer of funds to the agency.

10. Provision for definition of proper use of bonding funds made available to the agency by forfeiture, including possible establishment of trust fund for perpetual care.

11. Provision of written procedures for implementation of corrective action by the agency.

12. Provision of procedures for the establishment of a trust fund for perpetual care of the facility if need develops.

One method of assuring that an adequate period of binding is in effect at all times may be to initially require a twelve month bond and further require that an additional six month premium be paid at the end of each six month period thereafter. This requirement would provide the agency with six months of lead time to take any necessary action against a licensee who refuses to obtain further bonding.

PART IV RECOMMENDATIONS

The Task Force has concluded that a financial responsibility review system, as a prerequisite for certain licensees to possess and use radioactive material, should be instituted at both the State and Federal level. Bonding and perpetual care trust funds can, to a limited extent, serve as an integral part of the system but caution should be exercised in relying totally on bonding programs because of the possible restricted availability of large dollar amount bonds. The Task Force found surety companies reluctant to issue assurance bonds in excess of $1,000,000 unless secured by 100 percent collateral; nevertheless, it is the position of the Task Force that bonding and perpetual care programs be considered as the principal option of the total financial responsibility assurance. Accordingly, the Task Force submits the following for consideration:

1. It is recommended that the Executive Committee of the Conference accept this report for presentation to the Conference and implementation of the recommendations as appropriate.

2. Further, other alternatives to bonding and perpetual care trust funds have been considered and are generally not viable. It is recommended that the Task Force be discontinued and that the Executive Committee establish a mechanism for periodically assessing the viability of programs instituted and the need for additional effort in this area.

3. Further, it is recommended that each State consider the adoption of a bonding and perpetual care trust fund program as a portion of the total financial responsibility review system.

4. Further, it is recommended that Appendices C and D of the report be submitted to Task Force No. 6 for inclusion into the Council of State Governments Suggested State Regulations and Legislation.

5. Further, it is recommended that the NRC consider the adoption of a similar financial responsibility review system for certain licensees

that would include, as necessary, a bonding and perpetual care trust fund program.

6. Further, it is recommended that the Federal Government establish a policy providing for financial and technical assistance in taking remedial measures at the commercial radioactive waste disposal sites. *(In concurrence with the GAO report "Improvements Needed in the Land Disposal of Radioactive Wastes - A Problem of Centuries," dated January 12, 1976.)* Studies and remedial actions to be performed at ERDA radioactive waste disposal facilities should be accomplished with State radiological health program involvement.

APPENDIX A

SUMMARY OF THE COST ESTIMATE TO DECONTAMINATE THE AMERICAN NUCLEAR COMPANY

(Excerpts from "A Study of Radioactive Contamination at the American Nuclear Company Plant," Oak Ridge National Laboratory, November 1, 1973)

A facility with a "hot cell" operation and a storage well containing 50,000 curies of cobalt-60 and 18,000 curies of cesium-137 requires extensive decontamination. The facility has contamination throughout and has soil contamination due to waste treatment problems. The removal of the cobalt and cesium from storage, the welding shut of some doors, and decontaminating and securing the building to where the potential of public contamination is small would cost an estimated $145,000. To remove soil and decontaminate the building to the extent that unrestricted use of the property may be permitted was estimated to cost $1,000,000 to $2,000,000. One should note that the $145,000 would not cover the annual public cost to monitor or maintain the facility.

The estimated costs are as follows:

$90,000	decontaminate "hot cell"
33,000	decontaminate office
22,000	excavate hottest earth
$145,000	Total
(18,000	additional for fence around 15 acres.)

APPENDIX B

1974 NATIONAL CONFERENCE ON RADIATION CONTROL WORKSHOP #3 REPORT

What Are The Bonding and Perpetual Care Requirements For Waste Burial Sites?

Scope: This workshop is to consider the bonding and perpetual care requirements of State-licensed shallow land burial sites used for the disposal of radioactive wastes. Of particular concern is the problem of assuring sufficient funding to maintain, in perpetuity, the integrity and security of a waste burial site, including perhaps surveillance and monitoring. Similarly, the question of bonding to assure acceptable performance by the operator or to provide adequate operational funds in case of default by the operator needs to be explored.

PREFACE

As the scope of this workshop represents an extension of similiar past considerations of the Conference's Task Force on Radioactive Waste Management, the following report should be appended to the April 24, 1974 report of that Task Force.

Workshop No. 3 recommends that the Executive Committee adopt the following as Conference recommendations:

"The State should assure that:

1. A performance bond is posted by the burial site operator payable to the State agency having the responsibility for closing and maintaining the site in the event of default or other inability of the operator to meet the requirements of the regulatory authority or contract obligations. Such performance bond should be adequate to cover the following costs:

    a. The decommissioning of the site so as to require minimum maintenance.

    b. The payment of any funds due the perpetual care trust fund at the time of default.

    c. The maintenance and monitoring of the site for at least one year to permit possible site reactivation, if desired.

    Generally, this performance bond should be between $50,000 and $500,000, depending on site characteristics.

2. A perpetual care trust fund is legally established which should draw interest adequate to pay the costs of monitoring and maintaining the decommissioned site. The perpetual care trust fund should be identified and limited to the monitoring, maintenance, and other perpetual care at the radioactive waste burial site. The estimated costs of monitoring and maintaining the decommissioned site should be re-evaluated periodically, but not exceeding five years and the contract with the operator renegotiated as needed.

    Items to be considered in determining the pereptual care trust funds are:

    a. Surveillance, including salaries, travel expenses, instrument maintenance, overhead, and well drilling.

    b. Maintenance of site, including labor, salaries, overhead, special equipment (evaporators, etc.), fence repair, and erosion control.

c. Contingency fund, including potential protective actions to prevent unacceptable release of waste materials from the site, including land acquisition, and blocking procedures."

Generally, the annual interest from the perpetual care trust fund should be between $50,000 and $250,000 depending on site characteristics. $3,000,000 in a trust fund will yield approximately $150,000 in interest annually.

The perpetual care trust fund is the crux of the legal and financial matters to be considered. For the purposes of licensing, once radioactive material is buried it is no longer subject to the license possession limit. This is based on the concept that there is no intent to remove radioactive waste from the burial site and is the basis for the State assuming the responsibility for any costs of monitoring and maintaining the site after decommissioning. Prior to decommissioning, the license should be conditioned to require the operator to perform an adequate monitoring and maintenance program of the burial site, to both protect the public health and safety and to minimize future maintenance costs.

Once the radioactive wastes are buried in accordance with license conditions, any disinterment of the solid wastes resulting from changes in State or Federal regulations would be at State or Federal expense. Any disinterment of the solid wastes should only be performed under conditions specifically approved by the regulatory agency.

3. Nuclear Liability Insurance is posted in the amount of at least $1,000,000.

Regulatory authorities and other interested agencies should apply the above criteria to all future burial sites. Presently operating sites should meet the above criteria at the next license renewal and/or contract renewal.

Co-Chairmen: Aubrey Godwin, Alabama
Michael Christie, Idaho

APPENDIX C

SUGGESTED CHANGES TO THE SUGGESTED STATE REGULATIONS

Sec. A.2 Definitions

***

(bb) "Major Processor" means a user processing, handling, or manufacturing radioactive materials exceeding Type A quantities as unsealed sources or material or exceeding four (4) times Type B quantities as unsealed, sources, but does not include nuclear medicine programs, universities, industrial radiographers or small industrial programs. Type A and B quantities are defined in 10 CFR 71.4.

(bc) "Waste Handling Licensees" means persons who hold radioactive wastes for disposal and/or those who actually dispose of radioactive wastes.

(bd) "Ore Refineries" means all processors of a radioactive material ore.

(be) "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) Licensed Facilities" means nuclear reactors, or nuclear fuel reprocessing plants; or uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

Sec. C.25 General Requirements for the Issuance of Specific Licenses

***

(a) ***

(b) ***

(c) ***

(d) ***

(e) Bonding Requirements

(1) Pursuant to (cite provisions of the Act), and except as otherwise provided, a bond made payable to the (Director of the Agency) and in the amount specified in paragraph (e)(4) shall be posted to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the Act and these regulations.

(2) The bond required in paragraph (e)(1) shall be received by the (Agency) prior to issuance of a license. An acceptable bond is ______________.

(3) Amendments to licenses in effect on (the effective date of this regulation) may be issued providing that the required bond is received by the (Agency) within 90 days after (the effective date of this paragraph (e)).

(4) The following specific licensees are required to post a bond within the range of amounts specified:

(1) Major Processors ($100,000 - $5,000,000)

(ii) Waste Handling Licensees ($50,000 - $500,000)
(iii) Ore Refineries - Mills, with associated tailings piles ($500,000 - $5,000,000)
(iv) Formerly AEC or NRC Licensed Facilities ($50,000 - $500,000)
(v) All others except persons exempt pursuant to paragraph (e)(5) (Minimum of $1,000 - $10,000 to $500,000)) (A minimum bond shall be established if in the opinion of legal counsel it is necessary to meet State constitutional provisions on equality.)

(5) The following persons are exempt from the requirements of paragraph (e)(1) (A minimum bond shall be established if in the opinion of legal counsel it is necessary to meet State constitutional provisions on equality):

(i) All State, local, or other governmental agencies unless they fall in subparagraphs (e)(4)(ii) or (iii) above,
(ii) Persons authorized to possess no more than 1,000 times the quantity specified in Schedule B, Exempt Quantities, or combinations of radioactive materials listed therein as given in Note 1, Schedule B.
(iii) Hydrogen-3 contained as hydrogen gas in a sealed source,
(iv) Radioactive noble gases in sealed sources with no radioactive daughter product with half life greater than 30 days,
(v) Reserved (There may be others a State wishes to consider)
(vi) Reserved (There may be others a State wishes to consider).

(6) This paragraph (e) becomes effective on __________ (90 days after enactment of appropriate legislation or such time period as prescribed by the State Administrative Procedures Act).

(f) Perpetual Care Requirements

(1) Pursuant to (cite provisions of the Act), and as otherwise provided, a perpetual care trust fund shall be established prior to the issuance of a license.

(2) The following specific licensees are required to provide perpetual care funding. (Perpetual care funding may also be required for formerly ACE or NRC licensed facilities.)

(i) Waste Handling Licensees
(ii) Ore Refineries

Schedule B

Note 1

For purposes of Section C.25 (e) where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine the amount of each isotope possessed and 1,000 times the amount in Schedule B for each of those isotopes when not in combination. The sum of the ratios of those quantities may not exceed one (i.e., unity).

Example:

Amt. of Isotope A possessed

Example:

$$\frac{\text{Amt. of Isotope A possessed}}{\text{1000 x Schedule B quantity for Isotope A}} + \frac{\text{Amt. of Isotope B possessed}}{\text{1000 x Schedule B quantity for Isotope B}} \leq 1$$

APPENDIX D

SUGGESTED LEGISLATION FOR LICENSEE BONDING AND PERPETUAL CARE TRUST FUNDS

Section __________, Bonds

(a) The (Director of the Agency) or his duly authorized representative shall require the posting of a bond by licensees to provide funds in the event of abandonment, default, or other inability of the licensee to meet the requirements of the (Agency). The (Agency) is hereby authorized to establish bonding requirements by classes of licensee and by range of monetary amounts. In establishing such requirements, the (Agency) shall give consideration to the potential for contamination, injury, cost of disposal, and reclamation of the property.

(b) All bonds forfeited shall be paid to the (Director of the Agency) for deposit in a special fund by the (State Treasurer) called the (Radiation Reclamation Fund). All monies in such Fund are hereby appropriated and may be expended by (Director of the Agency) as necessary to assure the protection of the public health and safety. Monies in this fund shall not be used for normal operating expenses of the Agency.

(c) A bond deemed acceptable in (name of State) shall be a bond issued by a fidelity or surety company authorized to do business in (name of State), a personal bond secured by such collateral as the (Director of the Agency) deems satisfactory, a cash bond, or a letter of credit. (Acceptable bonds may be spelled out in existing State laws and this provision should be consistent with those laws.)

(d) All State, local, or other governmental agencies, or subdivisions thereof shall be exempt from the requirements of this Section __________. The (Director of the Agency) is authorized to exempt classes of licensees from the requirements of this Section when a finding is made that such exemption will not result in a significant risk to the public health and safety. (If a State constitutional problem exists, Section C.25 (e)(5) must be revised accordingly.)

Section __________, Perpetual Care Trust Funds

(a) The (Director of the Agency) or his duly authorized representative shall require a licensee to deposit funds, on an (annual, semi-annual, quarterly) basis, in a trust fund when it is deemed there is a reasonable possibility that the licensed activity may eventually cease to operate although still containing, or have associated with the site at which the licensed activity was conducted, radioactive material which will require maintenance, surveillance or other care on a continuing and perpetual basis.

(b) In order to provide for the proper care and surveillance of sites subject to paragraph (a) of this Section, the State may acquire by gift or transfer from another government agency or private person, any and all lands, building, and grounds necessary to fulfill the purposes of this Section. Any such gift or transfer is subject to approval and acceptance by the State.

(c) The (Department) may by lease or license with any person provide for the operation of a site subject to this Section for the purpose of carrying out the provisions of this Act. Any lessee or licensee, including all State, local, or other governmental agencies or subdivisions thereof, operating under the provision of this paragraph (c) shall be subject to (Section _____, Bonds).

(d) The funds required by paragraph (a) of this Section shall be established at such rate that interest on the sum of all funds reasonably anticipated as payable shall provide an annual amount equal to the anticipated reasonable costs necessary to maintain, monitor and otherwise supervise and care for the lands and facilities as required in the interest of public health and safety. In arriving at the rate of funds to be deposited, the (Department) shall consider the nature of the licensed material, size and type of activity, estimated future receipts and estimated future expenses of maintenance, monitoring, and supervision.

(e) All funds accrued as interest monies deposited in the perpetual care trust fund are hereby appropriated and may be expended by the Director to monitor and maintain the site as required to protect the public health and safety on a continuing and perpetual basis.

(f) Recognizing the uncertainty of the existence of a person or corporation in perpetuity, and that ultimate responsibility to protect the public health and safety must be reposed in a solvent government, without regard to the existence of any particular agency or department thereof, all lands, buildings, and grounds acquired by the State under paragraph (b) of this Section shall be owned in fee simple absolute by the State and dedicated in perpetuity to the purposes stated in paragraph (b). All radioactive material received at such site and located therein at time of acquisition of ownership by the State becomes the property of the State.

(g) In the event a person, licensed by any governmental agency other than the State of (name of State), desires to transfer a site to the State for the purpose of administering or providing perpetual care, a lump sum deposit shall be made to a trust fund. The amount of such deposit shall be determined by the (Director of the Agency) taking into consideration the factors stated in paragraph (d) of this section.

Section __________.

(a) The provisions of this Act are severable and if any part of the Act is declared invalid or unconstitutional, such declaration shall not affect the validity of the part which remains.

(b) This Act is cumulative and is intended to supplement existing laws, and no part shall be construed to repeal any existing law specifically enacted for the protection of public health and safety.

(c) The provisions of this Act shall take effect 90 days after its passage and approval by the Governor of its otherwise becoming a law.

TASK FORCE REPORT ON STANDARDIZATION OF RADIATION MEASUREMENTS

Thomas M. Gerusky, Chairman

The Task Force Report on Standardization of Radiation Measurements consists of six State representatives: Marshall Parrott, Oregon; Donald Van Farowe, Michigan; Ellen Haars, Iowa; Richard Bleumle, South Carolina; Paul Eastvold, Illinois; and Tom Gerusky, Pennsylvania. The four Federal resource representatives are: Sherman Fivozinsky, NBS; Bernard Weiss, NRC; Ray Johnson, EPA; and Thomas Ohlhaber, FDA.

The Task Force held an organizing meeting in Gaithersburg, Maryland, at NBS Headquarters on October 20-23, 1975. The Task Force, under a contract with NBS is responsible to review the needs of the States in regard to radiation measurement capabilities, both ionizing and nonionizing. We will attempt to determine the various areas where radiation control programs need assistance - calibration, survey procedures, laboratory procedures, and training - and identify areas in which NBS can provide assistance to States. The Task Force members in conjunction with the staff of NBS completed a questionnaire which was to be forwarded to all State and local radiation control agencies.

Following this meeting in October, the questionnaire was tested by having each State serving on the Task Force complete the questionnaire and send it back in for review. We were also held up, because the questionnaire had to be approved by the Office of Management and Budget before it could be sent out. Following the completion of the trial run, questionnaires were forwarded to all program directors. On April 6-8, 1976 the Task Force met in Las Vegas at the EPA laboratories to review responses. Partial responses came in from only 28 States, and I believe we have received an additional 5 since then.

A report of that review was forwarded to NBS on April 13, 1976. Future meetings will be held to update the results of the questionnaire, determine the needs of the States, and make recommendations to NBS on priority needs for States assistance. A final report must be submitted to NBS in early 1977.

I request that those States that did not send in a questionnaire, please do so. If we only have 35 responses, we may miss a very important concern that you have, and we want the report to NBS to be representative of all of the States, not just 35.

TASK FORCE ON COMMUNICATIONS

Donald C. Gilbert, Chairman

We recommend that the Task Force be disbanded. The report is out and I think updates are being mailed out. If you have any changes, send them into Sheldon Schwartz and we will make those changes. If you have any suggestions that we should put in the Desk Reference, send those in also.

THREE YEARS OF NEXT - AN ANALYSIS

Ralph E. Bunge
Division of Training and Medical Applications
Bureau of Radiological Health, FDA

NEXT completed the pilot-testing stage on October 1, 1972 and began accepting data on a routine basis. By the end of 1975, 42 States and local agencies had submitted surveys on over 19,000 projections. This paper will use the representative sample portion of this data base to show some of the analyses we are doing that can also be done by each State program based on currently available computer tabulations.

Let's look at the data. The first question that comes up is, "Are there any obvious trends appearing over the 3 years?"

For convenience, we have divided the 3 years into overlapping 12-month time periods (Fig. 1). This results in nine time periods each one overlapping the previous time period by 9 months. Notice that time period 1, 5, and 9 are the three separate non-overlapping years.

Figure 2 shows that some exposures appear to decrease. Figure 2 shows the mean exposure for the Dental Bitewing projection for each of the nine time periods, and a standard error band around the mean. Looking at other projections, some appear to be increasing (Fig. 3); for example, the Abomen (KUB). Others appear to remain about the same (Fig. 4), as shown here by the Chest (P/A). We could look at other projections that seem to go up and then down, or others that seem to go down and then up over the same time periods.

So the first conclusion is that there is no one statement that applies to all the NEXT examinations when we consider trends in Exposure at Skin Entrance (ESE). Of course, dramatic changes probably shouldn't be expected in all examinations over a 3-year period. Rather, we must analyze data on individual examination types if we are to make statements about trends.

Let's start with the Chest. Figure 4 shows the mean values fluctuating somewhat in the early time periods, and the trend curve flattening out in later time periods that contain more survey data. This, of course, doesn't imply that these data are not useful. On the contrary, it indicates that the data are consistent over time.

The Chest projection is the most commonly performed survey in NEXT and is the most common x-ray procedure performed in the United States. This makes this projection the bellwether of our system. If our data produced a mean value changing radically with time, then we would certainly question the system as well as the data.

Although we do not expect the mean ESE value to be changing much with time, the amount of data for chest surveys makes it possible to look at many factors such as the effect on ESE of different kVp techniques, the average exposure given at different types of facilities, or collimation used by credentialed or non-credentialed operators.

However, we will not cover all these details. Rather we are going to zero in on two of the other examinations which do appear to vary over time.

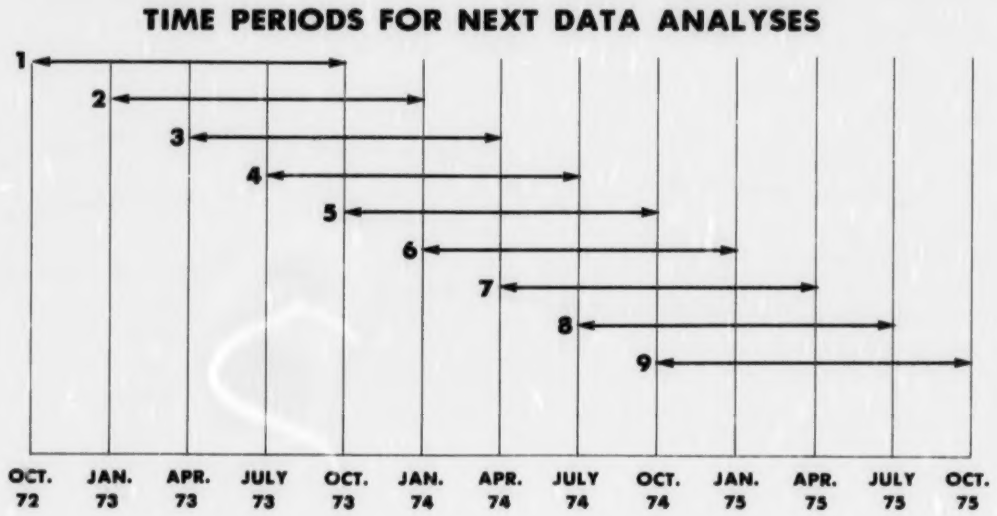

TIME PERIODS FOR NEXT DATA ANALYSES
1
2
3
4
5
6
7
8
9
OCT. 72
JAN. 73
APR. 73
JULY 73
OCT. 73
JAN. 74
APR. 74
JULY 74
OCT. 74
JAN. 75
APR. 75
JULY 75
OCT. 75

Figure 1.

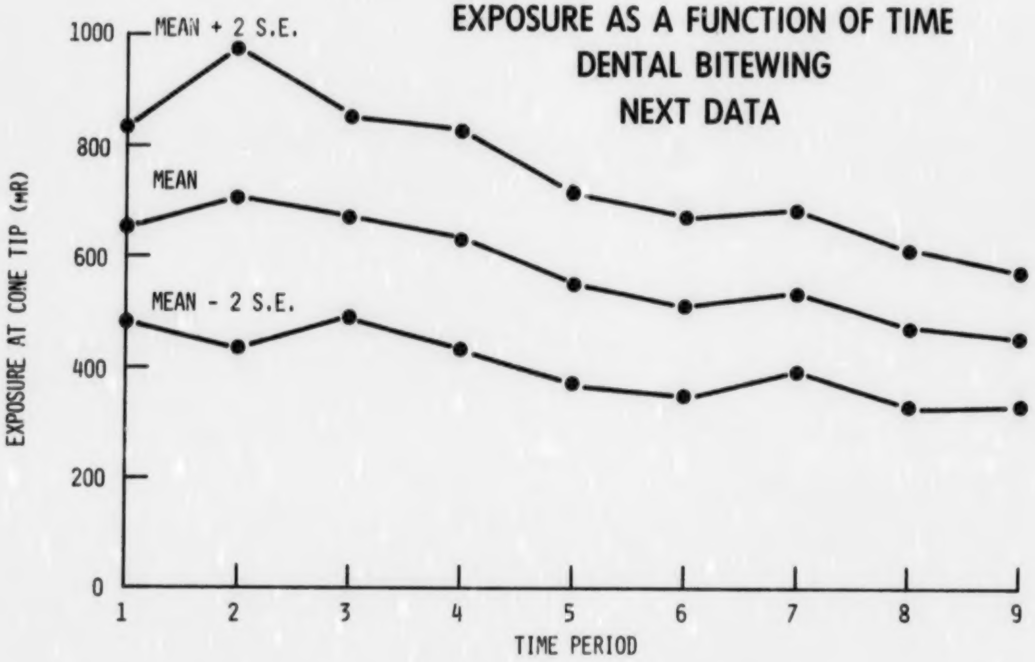


Figure 2.

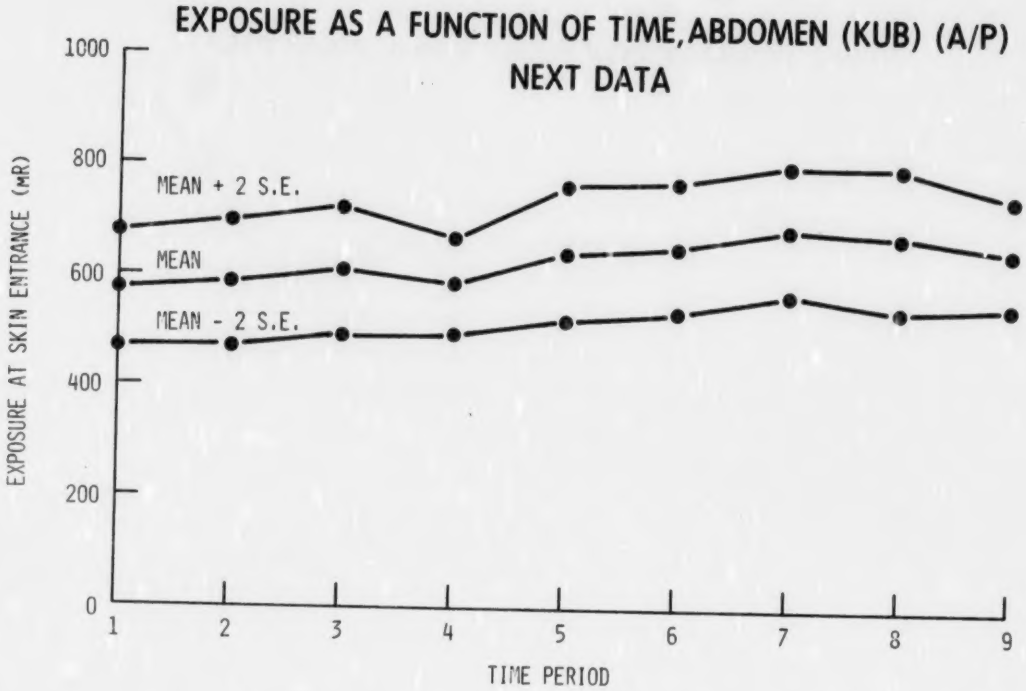


Figure 3.

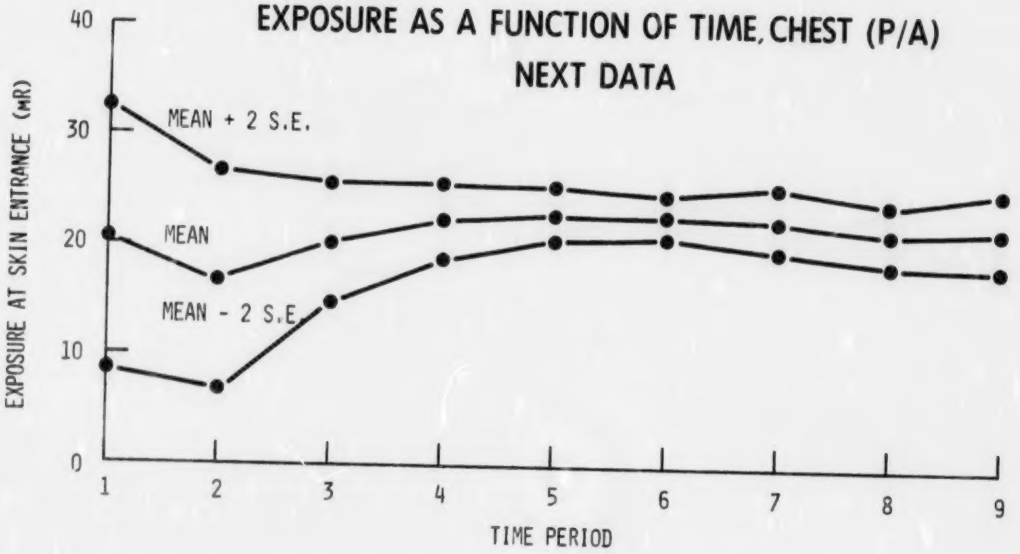


Figure 4.

First the Abdomen (Fig. 3). It appears that the mean ESE is increasing from under 600 mR to around 650 mR. "Is this real?" Is some factor operating in the real world of x-ray practice that has caused a shift toward higher ESE values over the last 3 years? Or, is there some other explanation for this apparent increase in mean ESE? The first point to make is that the difference between 600 and 650 is not statistically significant. However, this statement is not adequate, since data can be indicating trends before the differences are "statistically" significant. Let us look at the ESE frequency distributions for the three non-overlapping time periods 1, 5, and 9 (Figs. 5, 6, 7). At first glance, they appear to have the same general shape. However, looking at them in more detail, note the percentage of cases above 800 mR in each time period. Notice how this percentage increases from time period 1 to time period 5, and again for time period 9. This increase in higher ESE cases seems real, appearing in both weighted and unweighted data. More cases with higher ESE would, of course, raise the mean values in the later time periods. Again, the data seem consistent, but is this a "real-world" phenomenon?

In an effort to get a better handle on this change, we looked at the distribution of kVp's for time periods 1 and 9, and found that time period 9 had a larger percentage of lower kVp cases than time period 1, with lower kVp tending to give higher ESE's. So the question remains, do these data point to a real trend, or is the ESE from one time period more representative of the real world? At this time we can only hypothesize, but: (1) from the fact that time period 1 has fewer surveys (270 compared to 440 form time period 9) and (2) from looking at other frequency distributions which generally show higher exposure tails, more like time period 9, we hypothesize that time period 9 is more representative of the real world, and that the latter part of the trend curve (Fig. 3) provides better data. We tentatively conclude, in the absense of supporting data, that there has not been a real shift to lower kVp techniques for the Abdomen examination, and that the mean ESE is not really on the increase. We will observe that data closely over the next few time periods. Our expectation is that the mean ESE will now remain rather constant unless there is some strong influence to raise or lower it.

Let's look at the trend line that appears to be going down (Fig. 2). The first question is whether this trend is real. The change here is greater than in the case of the Abdomen, but even here the decrease is not statistically significant, although it looks like it may well be, within a few more time periods, if the present trend continues.

Again, it is instructive to look at the frequency distributions of exposure for the 3 years (Figs. 8, 9, 10). Note that the percentage of films with exposure at cone tip above 1000 mR is decreasing from time period 1 to time period 5 and again to time period 9. This is consistent with figure 2 showing a decrease in the mean exposure over time and shows how a reduction in the percentage of films with high exposure will bring down the average exposure.

It is also interesting to look at the first and third quartiles (Fig. 11) over the nine time periods. We see that the first quartile has remained fairly stable at around 220 mR. But we see that the percentage of high-exposure cases has dropped dramatically, with the third quartile going from 900 mR in time period 2 to 500 mR in time period 9.

Some convincing support for the contention that this reflects a real-world decrease in mean exposure for dental films comes from the X-Ray Exposure Study of 1970. In 1970, B-speed dental film was still being produced and average exposures were higher. However, we can look at just those exposures done with D-speed film (Fig. 12) and we see a distribution very similar to time period 1 of NEXT data (Fig. 8).

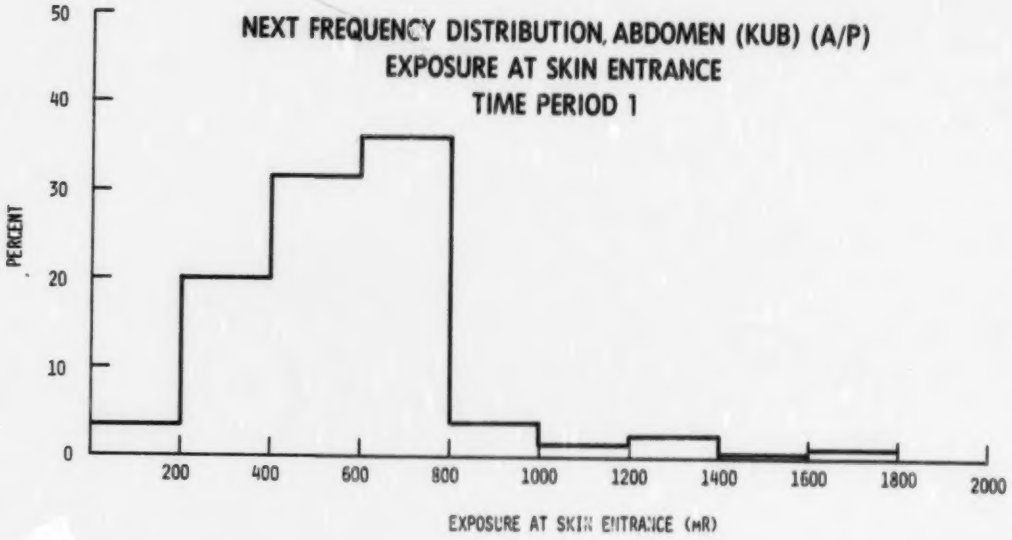


Figure 5.

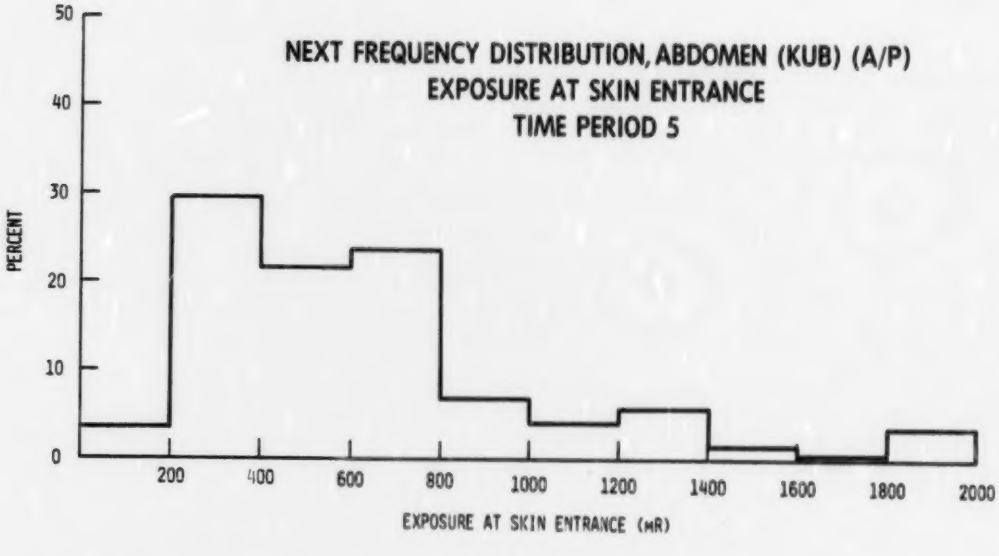
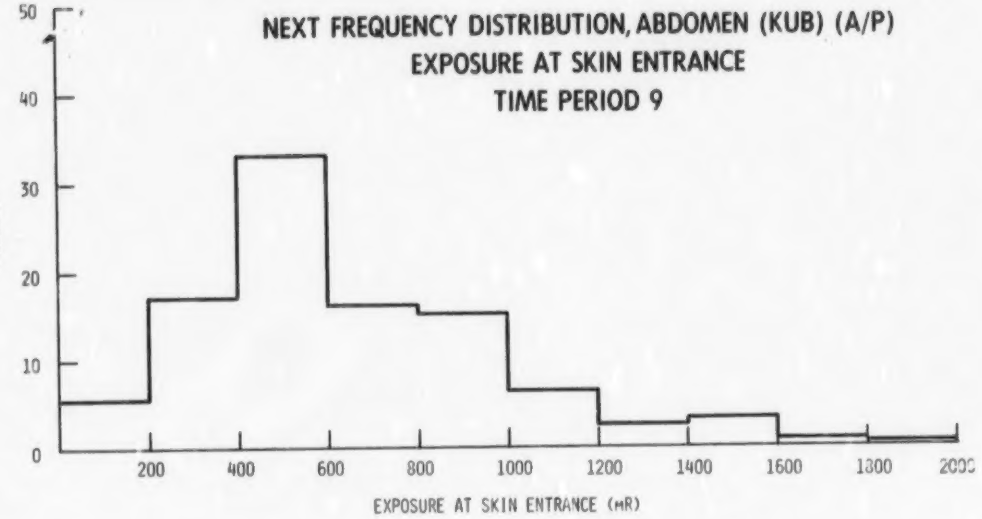


Figure 6.



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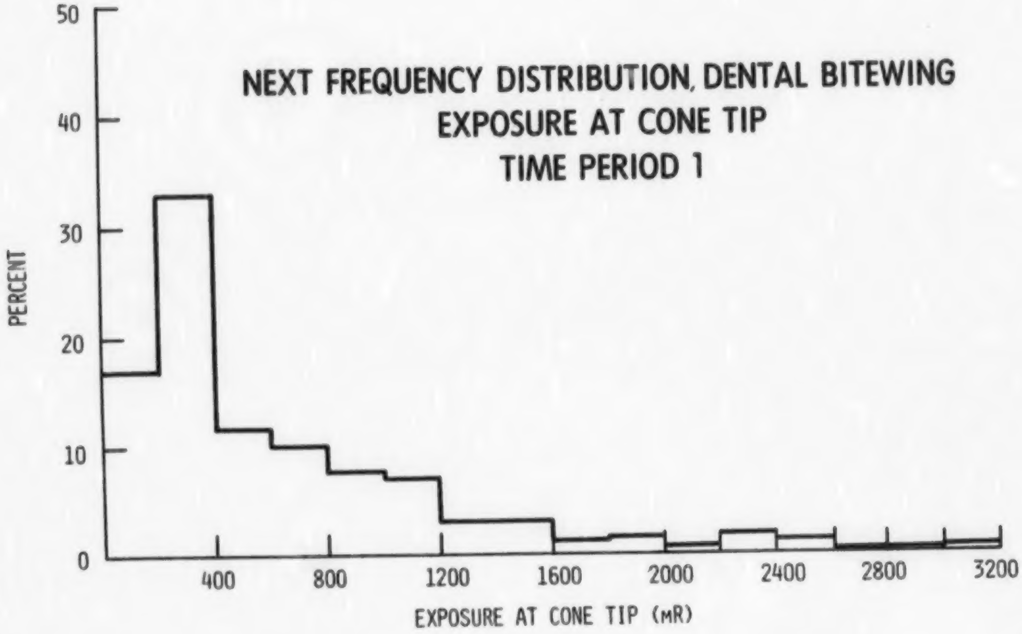

Figure 8.

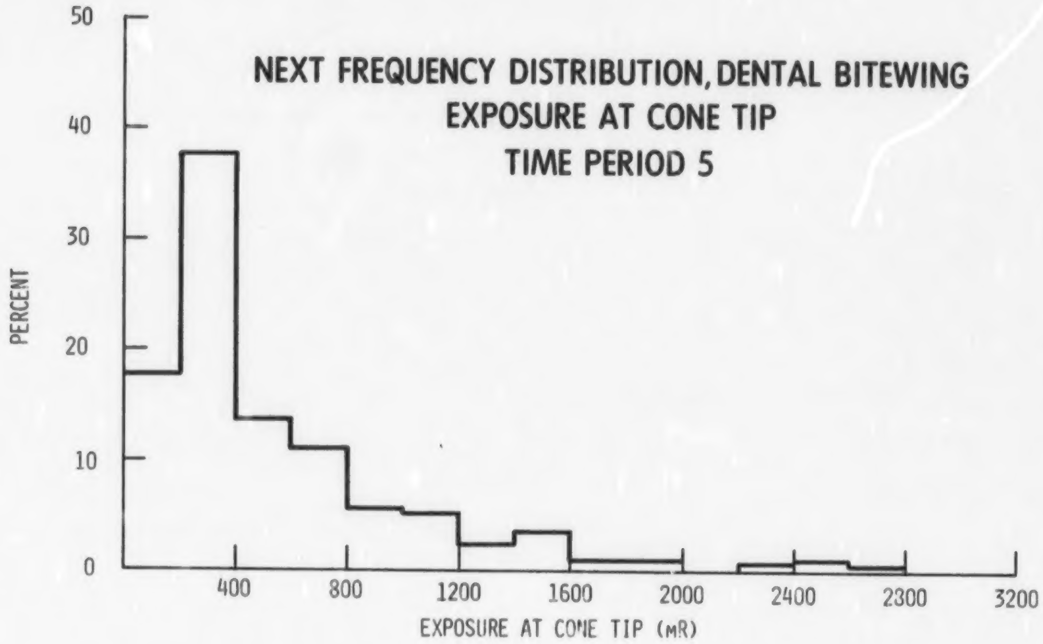

Figure 9.

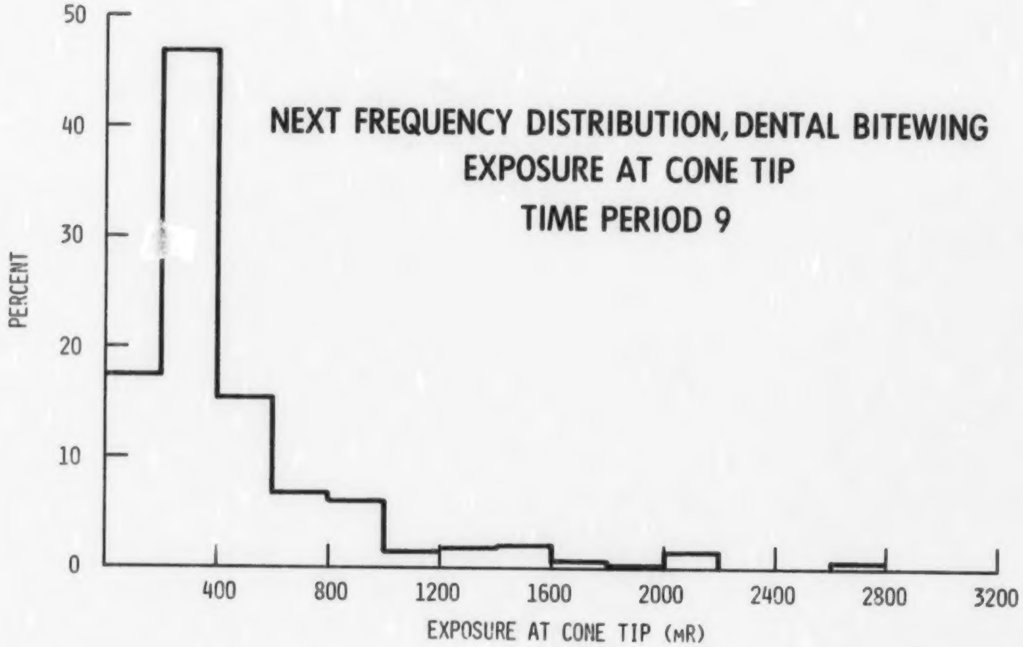

Figure 10.

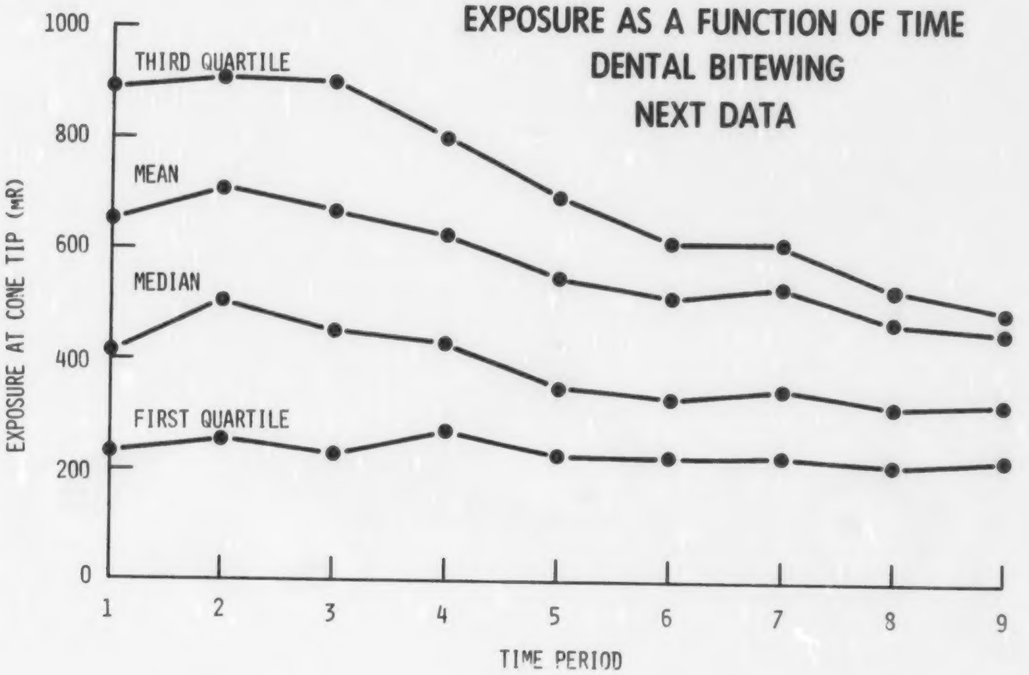

Figure 11.

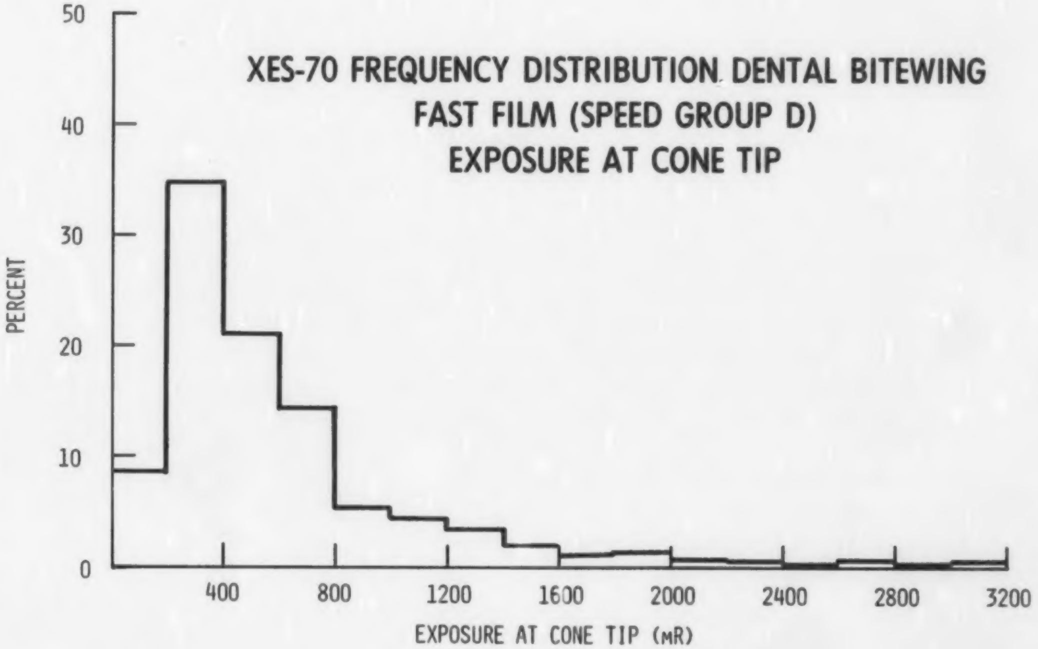

Figure 12.

Thus we think that NEXT is accurately reflecting the switchover to faster dental film. Note that Next data alone are not sufficient to firmly establish this conclusion, since we do not collect data on film speed.

In addition, State radiological health programs may well have played a significant role in eliminating the high-exposure films, but again, "All States" NEXT data per se do not yield that information. However, some individual States that have been active in dental exposure reduction programs do show lower results in NEXT dental projections.

In conclusion, I would like to stress two points: (1) First, there are as yet no statistically significant trends in the data we looked at; however, there are indications that real changes in the data may be occurring, and it will be interesting to follow these over time. Irrespective of trends, this collection of 3 years of data provides a solid "baseline" with which to compare individual cases or future trends. These basic mean values (Fig. 13) for the NEXT examinations were sent to the States with the June 1976 NEXT Newsletter.

We should point out that this data base will be retained for additional analyses and future comparisons can be made to this same base. We hope to publish a more detailed analysis as a BRH Technical Report. We should also point out that several individuals and agencies have been provided with various elements of the NEXT data files. Numbers that they have produced may not agree with our current numbers. It is necessary to be aware that the NEXT file changes not only with the addition of new cases but also as old cases are corrected or post-edits are verified. Caution is especially necessary in making sweeping statements about trends in NEXT data without considering the error limits.

THREE YEARS OF "NEXT" DATA
ESE (mR)

Projection	1st Qtr.	Median	3d Qtr.	Mean
CHEST (P/A)	11	16	26	22
SKULL (LAT)	130	230	310	250
ABDOMEN (KUB)	380	530	730	600
RETROGRADE PYELOGRAM (A/P)	470	560	790	620
THORACIC SPINE (A/P)	540	980	980	830
CERVICAL SPINE (A/P)	140	230	310	260
LUMBO-SACRAL SPINE (A/P)	450	700	1100	810
FULL SPINE (A/P)	160	230	330	270
FEET (D/P)	60	110	200	230
DENTAL BITEWING (POST)	220	330	630	510
DENTAL PERIAPICAL	220	360	700	580
DENTAL CEPHALOMETRIC (LAT)	20	30	40	40

Figure 13.

The second point is that all of the NEXT data presented here were graphed from NEXT outputs that are either routine tabulations or are available on request as computer-calculated frequency distributions. With this data easily available, we hope NEXT participants will take a little time to look at their own data, ask questions form hypotheses, and then search for the answers with a detailed look at the data. We stand ready to help in the search.

DISCUSSION

DR. SOLON: NEXT data clearly shows individual exposures. Is it part of the NEXT program to determine population doses and trends in population doses, factoring in the number of individuals receiving x rays?

MR. BUNGE: Not directly. The NEXT system does not give data simlar to that from X-Ray Exposure type studies. XES type studies are done on a statistical sample of the U.S. population. NEXT does not give this type of data for two reasons: (1) NEXT is a machine or facility based survey, so we get a representative sample of facilities, not of people. We do not attempt to get comprehensive data on the number of x rays individuals receive. (2) We determine exposure for a standard-size patient; we do not take into account variations due to patient size or other characteristics. So we lose something in population data but we gain an exposure index that can be compared from facility to facility.

IS THERE A NEED FOR NATIONAL RECOMMENDATIONS ON THE QUALIFICATIONS FOR MEDICAL RADIATION TECHNOLOGISTS?

Norbert P. Heib, Jr.
Division of Training and Medical Applications
Bureau of Radiological Health, Food and Drug Administration

Most medical x-ray protection activities to date, whether voluntary or legislatively enforced, have been concerned with the conduct of radiologic examinations, with particular emphasis on the type of facility where such procedures are performed. These activities have included registration, regulation and inspection of equipment, promulgation of standards for manufacture of new equipment, and specification of x-ray room design and construction. Although many of these activities have reduced unnecessary patient exposure, the x-ray technologist can exercise his or her judgment relative to the conduct of the examination and thus has considerable influence on patient exposure. The technologist controls and/or chooses parameters such as technic factors, patient shielding, collimation, film and screen speed, and processing variables. All of these have a significant effect on patient dose and have only recently been addressed in current radiological health programs.

There are approximately 130,000 persons operating medical diagnostic x-ray equipment in the United States. About 73,000 of them are credentialed; that is, they have demonstrated their competency through voluntary registration or mandatory State licensure. The remaining 57,000 comprise a non-credentialed group whose actual numbers and levels of training can only be approximated.

A number of programs and surveys have documented that medical radiation users are not performing at an optimal level. The Nationwide Evaluation of X-Ray Trends (NEXT) program has provided us with limited information on the job performance of x-ray technologists. The results to date show that 43 percent of the credentialed operators surveyed failed to properly restrict the x-ray beam to the size of the film for chest examinations, while 63 percent of the non-credentialed operators failed to do so. This indicates that in actual practice, the overall performance of x-ray technologists, whether or not they are credentialed, is not satisfactory, and further, that credentialed persons perform somewhat better than those who are not credentialed. NEXT surveys also show great variation in patient exposure among different facilities performing the same examination. For example, the range of exposure utilized for chest examinations was 2 mR - 193 mR. Data from other examinations show similar variations in patient exposure, approaching or exceeding 50-fold.

Another indicator of technologist performance is the field-trials of the HEW sponsored proficiency examination for diagnostic radiologic technologists. The test contained 230 questions and was divided into seven subject matter areas. It was pre-tested on a population of entry-level technologists, comprised of 666 credentialed (registered or licensed) individuals and 225 non-credentialed persons, all of whom performed general-purpose examinations. In all of the subject areas, credentialed x-ray technologists achieved higher scores than non-credentialed individuals, but neither group performed satisfactorily. However, on the entire test, only 1 percent of non-credentialed and 15 percent of credentialed individuals achieved the suggested criterion-references passing score of 85 percent.

A study of technics used in mammographic procedures in eastern Pennsylvania disclosed that radiation exposure of the breast could vary by a factor of 200 from facility to facility. Although some of this variation is due to legitimate differences in the x-ray technics selected, a significant proportion of the high exposures were caused by poor practices on the part of those individuals who operated the x-ray machines.

Although there are numerous accreditation and credentialing efforts to upgrade the competency of technologists being carried out by Federal and State agencies as well as professional organizations, the underlying problem associated with these activities is non-uniformity in the requirements. This accounts for varying levels of proficiency and restrictions on upward and lateral mobility of radiological health workers. The discrepancies in existing standards and those which may develop as a result of newly-implemented programs clearly indicate a need for some type of standardization among credentialing systems.

In a 1971 report, "Licensure and Related Health Personnel Credentialing," the Department of Health, Education, and Welfare recommended a moratorium on State legislation which would establish health occupations with statutorily-defined scopes of functions within a particular State. This moratorium was extended in 1973 for an additional 2 years in order to allow the Department sufficient time to evaluate the growing number of standards and recommendations in the field of manpower credentialing and to formulate recommendations for Departmental consideration. To facilitate these efforts, a Subcommittee on Health Manpower Credentialing was established and has developed a number of draft recommendations which could be utilized to upgrade and monitor the quality of health care rendered. One of the recommendations would provide for the development of national standards for selected health occupations.

In keeping with Departmental policy and in order to systematically upgrade the performance of x-ray technologists, the Food and Drug Administration's Bureau of Radiological Health is proposing a program which would establish recommendations concerning the qualifications for medical diagnostic x-ray and nuclear medicine technologists.

Because of the complex nature of the endeavor, it appears more desirable and feasible to evaluate the specific requirements for the qualifications of diagnostic x-ray and nuclear medicine technologists separately, than to address all x-ray users. This will allow for flexibility in the composition of advisory committees, which will develop the recommendations, so that input from appropriate medical and allied health organizations, State licensing agencies and Federal groups can be obtained.

As previously mentioned, poor patient protection practices on the part of x-ray technologists are due in part to the inadequacies and non-uniformity among existing standards for education and training and personnel credentialing. Our ultimate goal in this area is to develop and promote the use of recommendations which are (a) comprehensive enough to encompass all of the technologist's activities relevant to both patient care and protection; (b) sufficiently flexible to allow for various means of entering the field; and (c) uniform among the various standard-setting groups.

Because of the large number of Federal, State, and private sector organizations interested in credentialing of medical radiation technologists, the first step will be to identify and gather information pertaining to all existing standard-setting groups. Subsequently, representation from appropriate Federal and State programs and the private sector will be sought to discuss common elements in existing requirements which could be integrated in a uniform set of recommendations.

The prime goals of the project are to insure that each individual in the work force is screened through a credentialing system to determine his or her competence and to serve as a mechanism to systematically upgrade non-practitioner medical radiation users. The Bureau of Radiological Health believes that these goals can best be met through the development of a national set of credentialing recommendations and implemented by Federal, State, and professional organizations.

We hope that the Conference will support us in this endeavor and provide us with direct assistance by appointing representatives to participate in the development of the recommendations.

DISCUSSION

DR. SOLON: Yesterday we heard three thoughts from Dr. Nader, Dr. Wise, and Dr. Brown. Would you say that, in terms of the findings of your investigation, that you have supported or contradicted some of the assertions that were made, in terms of the quality of diagnostic radiology; the risk that are associated thereto? I found your numbers absolutely astonishing. I did not hear any moans, but you hear that 1 percent of the uncertified and 15 percent of the certified technologists - the people that are the infantry of radiological practice - appear to have qualifications, or credentials, or capacities which are unrelated to the function they are doing. I would think what you have to say as a high degree of relevance to what Dr. Nader, Dr. Wise, and Dr. Brown have said, I was wondering how many reacted at all.

MR. HEIB: I think the data bases that we have looked at have demonstrated that there are these problems, both with the credentialed technologists and the noncredentialed technologists. I would like to point out that probab., of all the credentailing professional organizations, the ARRT is probably one of the better ones. This project hopefully will ultimately allow for a systematic upgrading of the credentialed technologists and would also provide that noncredentialed technologists would have to meet some kind of efficiency criteria.

DR. PAGAN: I would like to make a comment. I think that we are talking about the "infantry" and I think we should go into the "military schools" in this case. I think that we should do something about the schools of technology. There we have to do something regarding the people who are teaching the technologists. In that area, I think there is a big problem. We have a lot of private and public schools, and perhaps there is a need for upgrading the schools - do something nationwide, in the sense of standardization of a curriculum, and also the upgrading of the teachers.

MR. HEIB: Thank you. I did not mention in the presentation that the advisory committee to FDA will address those issues such as the accreditation process itself, the curricula, the instructor qualifications, the number of clinical hours, and so forth; those will be addressed.

FROM THE FLOOR: I did not remember that you mentioned what the time frame was for completing the evaluations of licensure requirements and what is needed for the technicians. Do you have a projected time frame as to when licensing recommendations will be available?

MR. HEIB: First of all, I would like to point out that these are not licensing recommendations. They are recommendations on standards that can be utilized by Federal, State, and professional organizations. We have a time frame of about 2 years. This is both for nuclear medicine technologists and x-ray technologists. The working groups will meet, we will ask them to develop the recommendations; they will then be published.

MR. GERUSKY: Are you recommending, then, that we continue this moratorium until you have finished or not?

MR. HEIB: As you know, the moratorium on State licensure ended in December of 1975; there is no longer a moratorium. Our recommendation is not that the moratorium be postponed.

DR. FRITZ: I am just wondering what is going to be different about the program that you are recommending compared to the current system of credentialing? Is it going to make up for the approximately 60 percent of credentialed technologists who failed to perform adequately on that collimation standard and the 85 percent (I believe it was) who did not score adequately on your test? The second question was, are you considering therapy technologists in this program?

MR. HEIB: To answer your second question first, because of the nature of the problem and the issues to be addressed, hopefully, we are going to be doing it in phases; nuclear medicine technologists and diagnostic technologists first. Then, if we can reach a concensus with the organizations, the States, and the Federal agencies involved, we will move into other areas.

Hopefully, the process and the recommendations coming out pertaining to the curricula and accreditation process, will allow for improvement in the present school system; instructor qualifications and that kind of problem.

DISTRICT OF COLUMBIA'S EVALUATION OF THE ADMISSIONS, PRE-EMPLOYMENT, AND ANNUAL CHEST X RAYS

Richard A. Lane
Chief, Bureau of Occupational and Institutional Hygiene
and Radiological Health
Environmental Health Administration
District of Columbia

In 1964, Dr. Donald B. Chadwick, former Chief, Division of Radiological Health in the Public Health Service stated that "enough is known that practitioners of medicine, dentistry, and public health should make every feasible effort to prevent or reduce all unnecessary radiation exposures." He also stated, "The size of the population at risk and the possible consequences of failure to take appropriate action are too great."

The Committee on Biological Effects of Ionizing Radiation of the National Academy of Sciences stated unequivocally in its 1972 report that "medical radiation exposure can and should be reduced considerably by limiting its use to clinically indicated procedures, utilizing efficient exposure techniques and optimal operation of radiation equipment."

A recent 1973 policy statement issued by the Department of Health, Education, and Welfare entitled, "The Chest X Ray as a Screening Procedure for Cardiopulmonary Disease," states that: "Chest x-ray surveys among the general population are not productive as a screening procedure for the detection of tuberculosis and should not be done. The chest x-ray examination should be restricted to positive reactors to the tuberculin test." Every x ray exposes the patient to radiation and our present knowledge indicates that all exposure to radiation is believed to pose some risk of genetic or somatic harm to the recipient. Therefore, unnecessary x ray should be avoided. In view of the undesirability of using radiation without clear evidence of significant benefit, the liaison committee of the American College of Radiology and the American College of Chest Physicians have endorsed the HEW policy statement.

The BEIR Report of 1972 urged the restriction of the "use of radiation for public health survey purposes, unless there is a reasonable probability of significant detection of disease." There is sufficient evidence that certain nonselective mass screening radiographic procedures do not provide sufficient diagnostic health rewards for costs incurred.

Chest x-ray examination is by far the most common type of roentgen study performed. One and one half billion dollars are spent annually in the United States on chest x rays. This is based upon 70 million annual chest examinations with a cost to the medical consumer of $20 per examination.

Vital and Health Statistic, Volume of X-Ray Visits - United States April - September 1970, indicates that of all areas of the body being x-rayed, forty-eight percent of the hospital x-ray department workload are chest examinations and there has been a continuous increase in chest examinations from 1961.

Mr. Villforth, in his opening remarks to this distinct group's 6th Annual Conference in San Antonio, Texas, extrapolated figures from the BEIR Report to show that two individuals of the 50,000 who are season ticket holders of the Redskins football games will die as a result of unnecessary medical x rays. That is 8,000 deaths for the United States in one year.

Present District of Columbia Regulations (Health Care Facility Regulation #74-15; Title V Skilled Care Facility Standards, Title 8: Health Regulations, Chapter 7, Hospitals and Clinics, D.C. Housing Regulations Governing Hospitals and other Patient Care Facilities) require that all employees have a chest x ray upon employment and annually thereafter as a means of determining that the employee is free from active tuberculosis or carrier state. Thus the purpose of the chest x-ray is to screen employees for active cases of tuberculosis.

Presently there are 17 hospitals and 18 nursing homes in the District of Columbia that employ 20,500 people who are subject to these requirements, during the past 8-1/2 years, there has not been one case of tuberculosis found among employees at D.C. General Hospital who have been subjected to this screening program. This absence of tuberculosis among D.C. General employees implies that the incidence of TB among this select population is not different from that general population referred to in the DHEW policy statement and, therefore, the requirement for the employment and annual chest x rays is not needed. The same degree of protection can be obtained by the use of intradermal tuberculin test (purified protein derivitive (PPD), mantoux, or tine test), with positive reactors given a full size x ray.

The administration of this chest x-ray screening program to the 2200 employees of D.C. General Hospital costs $46,200 annually (2,200 employess plus 5 percent turnover rate at $2,000).

Over the past 8 1/2 years this program has cost $392,700, and has found no cases of tuberculosis. The same program utilizing the tuberculin skin test would cost $5,775 annually and $49,087 over the past 8-1/2 years. At a savings of $40,425 annually and $343,612 over the past 8-1/2 years, the same degree of protection could have been achieved.

Extrapolated to the other 18,200 health care facility employees, this mandatory x-ray screening program costs $366,000 annually to administer. Replacement of the chest x ray with the tuberculin skin test would cost $45,000 annually (18,200 X $2.50) a savings of $320,250 annually. This savings could be passed on to consumers in the form of reduced health care costs.

The estimated aggregate chest exposure at skin entrance for the 20,500 employees subject to the laws is (20,500 X 31.6) 647,800 mR annually, an estimated 90 percent of which could be eliminated through the use of the tuberculin skin test.

We believe that from both a cost-effectiveness point of view and a radiological public health point of view, the present chest x-ray screening program is both costly and nonbeneficial.

In view of the above information, the Department of Environmental Services recommended to city counsel that the following changes be instituted in the aforementioned regulations dealing with health care facilities in the District of Columbia. The recommended changes are as follows:

1. Health Regulations, D.C. Title 8: Chapter 7, Part - I - Hospital Regulations 107(D) - Line 8 ... Intradermal Tuberculin Test or Chest X Ray, delete; "or chest x ray" Add: "positive reactors to tuberculin test shall have a chest x ray."

Recent visits of 14 of the 17 Washington, D.C. hospitals and consultations with administrators regarding admission x rays proved that this paper could be entitled, "No Rhyme or Reason." Two of the largest hospitals stated that all patients regardless of age or reason for admission received a chest x ray as a matter of hospital policy. One additional hospital indicated all admissions over 18 years of age must be x-rayed. There appears to be some uniformity regarding admission policy in six D.C. hospitals. These hospitals x-ray new admissions on doctors' orders only. It was not determined if doctors had standing orders for x ray on all their new admissions. One additional hospital does routine chest on all admissions over 40. Two hospitals required x rays on all surgical patients over 40 years of age, one hospital on all surgical admissions, one hospital x-rays all surgical admissions over 14 years of age; as you can see, "NO RHYME OR REASON."

D.C. is second only to the city of Baltimore in the incidence of TB which appears to be on the increase in both cities. It has been established that this increase as well as the incidence of TB is primarily confined to skid row inhabitants. As stated earlier, D.C. General Hospital, providing medical care to that segment of the population which shows a higher incidence of TB has not detected one case of TB among its staff in 8-1/2 years, in their annual employee x ray.

A recent survey of the environmental conditions at the D.C. jail was conducted. While waiting to meet with the administrator a discussion was held with the medical director of the D.C. Penal System. It was stated that 14,000 individuals are processed through the D.C. facilities annually. Each of the individuals receive a chest x ray and only three individuals were discovered to have active TB.

It can be stated that this small number, 0.02 percent, was worth the cost and effort. However, I suggest you recall Mr. Villforth's statement of 8,000 deaths from unnecessary radiation. It has been stated to me that x ray is the worst diagnostic tool available in detecting TB. If this is true how do we justify the continued use of x ray for determining the presence of TB?

As reported by the Center for Disease Control, the refugees from Vietnam, 25,000 persons 15 years or older, were x-rayed. Four hundred and sixty-six had suspicious films and 16 of these had positive sputum. A little better percentage than D.C. jail experience, but do we need to x ray, skin test, and then sputum test?

Insurance companies are putting pressure on hospital administrators to include x ray as part of annual physicals of their employees. This procedure or request has been verbal and has not been in writing but it has been discussed with hospital administrators when it becomes time to renegotiate insurance contracts.

X rays have become a negotiable item on various contracts; teachers, policemen, firemen, and laborers in government.

It can be asked why my concern in this area? Be reminded of Don Chadwick's statement, "The possible consequences of failure to take appropriate action are too great."

The District has enthusiastically, as have many States, pursued the dental and medical Surpak, DENT, NEXT. (We have heard it said, why bother about dental exposure, everything has been done.)

However, D.C. experience with DENT has been most beneficial to the dental patients. For the first time by the use of the DENT program, we have ascertained the reduction of radiation exposure brought about by our field efforts. Two thousand roentgens have been eliminated from an area where it has been said no problem exists. And now Mammography (BENT). It is my opinion that the reduction of radiation exposure can best be effected by the elimination of unnecessary x ray.

Recently, I received a request for a copy of the forerunner of this paper from one of our comrades. On the envelope in which I received the request a logo indicating a PFG unit and stating "A chest x ray can save your life." You know, we still have a long way to go.

Another excellent example that I would like to site happened recently in two D.C. metropolitan hospitals. On June 15, 1975, a woman 40 years of age received an annual employee chest x ray consisting of three exposures and at the same hospital on August 10, another chest x ray. She was then sent to another hospital in the area on September 4, and as an outpatient she had three x rays; chest, kidney, and lower GI. The hospitals are less than 1 hour driving time apart. Therefore her x ray of June 15 and August 10 could have been made available. On September 15, she had a D & C plus three more chest x rays; September 21, a radium implant and three more chests; October 12, another implant, three more chests. Then in November a hysterectomy and three more chests. Then finally before death on November 24, one more final chest while in a coma. Have we come a long way or do we have a long way to go in reduction of unnecessary radiation?

A figure of 30 percent of all x rays absorbed by Americans do no good has been making the rounds. Leonard Woodcock, President of the United Auto Workers, wrote that 30 percent of all x rays currently being taken are either inaccurate or unreadable. Sidney Wolfe lifted the 30 percent figure from Priscilla Law, who quoted Jim Potchen, a master degree student at MIT. Mr. Potchen's statement is that 30 percent of all radiographs are inefficacious and are performed for reasons other than the health care of the patient.

The pneumoconiosis program experience shows that 30 percent of the chest exams were subclinical, therefore it stands to reason that 30 percent of all other chest exams are subclinical or lack quality.

It has been said where do we go in medical x ray? All of the units have filters, new automatic collimator, electronic timers and now a functional PL 90-602. What is left for us to accomplish that will reduce unnecessary radiation? Without doing the calculations, an assumption could be made that exposure to unnecessary radiation could be reduced by half, simply by eliminating x rays that do not provide health care to the patient.

NRC (formerly AEC) is accredited for establishing the term "as low as practicable" which has related primarily to nuclear reactors. This may or may not be true, but regardless of who coined the phrase, I suggest, No, I strongly urge that we who work for radiation protection from x rays adopt and heartily support the connotation.

ILLINOIS' PATIENT EXPOSURE LIMITS - AN UPDATE

Maury E. Neuweg
Illinois Department of Public Health

As most of you are probably aware, Illinois has taken a somewhat different regulatory approach to the reduction of unnecessary radiation exposure to patients from dental and medical x-ray sources. Various regulatory and standard-setting steps have historically been taken by States and Federal agencies in efforts to reduce patient diagnostic exposure. The Federal x-ray performance standards, for example, have been developed and implemented to provide optimum equipment for medical and dental radiation users. New types of x-ray film and fluorescent screens are being tested and evaluated in an effort to provide the user with the best quality diagnostic radiography while reducing patient exposure. These recent accomplishments have had quite an impact - both technically and economically - on the radiography diagnosticians. Illinois supports these steps forward in the field of x-ray protection and hopes that exposure reduction efforts will remain on top of regulatory efforts. Our approach and philosophy concerning patient exposure reduction is somewhat different, in that we are utilizing regulated limits as an enforced educational tool to achieve our desired goal.

At this point, I should regress a little and give you a brief history or our rationale for establishing the exposure limits and our methods of implementation. In 1969, the Illinois Department of Public Health began accumulating specific radiation patient exposure data. These data were derived from regulatory inspections of various radiation facilities throughout the entire State. During that time, patient exposure data were routinely collected from registrants using photographic x-ray machines. We found during our inspections that radiation exposure to patients varied as much as 10-fold. Since mass screening involved a significant percentage of the population, this extreme range of exposure was the prime factor in stimulating further regulatory research and evaluation. We then began to place emphasis on determining the amount of radiation actually required to obtain an adequate diagnostic radiograph. Once an appropriate level was determined, we then began to evaluate those facilities exceeding this level. After analysis of these field data, it was apparent that 75 percent of all facilities could obtain a quality diagnostic radiograph with less than 200 mR per exposure.

Therefore, a precedent was set by establishing patient exposure limits at the 75 percentile level. It was rationalized that if 75 percent of all facilities could obtain a quality radiograph within that prescribed level, then the upper 25 percent should be identified and required to meet this criterion.

This rationale was again applied when we established the dental bitewing exposure limit that became effective on January 1, 1973. Two lears later, on January 1, 1975, four medical radiographic examination exposure limits also became effective. The four examinations - AP Abdoman, PA Skull, AP Cervical Spine, and Lateral Lumbar Spine - were chosen since the direct beam particular to these routine studies impacted either on the surrounding genetic material or major critical organs. Baseline data for the dental and medical exposure limits have been collected since April of 1971. Nearly 3,000 bitewing exposures were used to determine the dental exposure limit. The medical exposure limits were developed after reviewing nearly 2,000 AP Abdomen exposures, 900 Lateral Lumbar Spine exposures, 300 Cervical Spine exposures, and 450 PA Skull exposures. The

75 percentile level of the aforementioned exposures again was chosen as the mandatory limit.

Now that the foundation has been established regarding the dental and medical exposure limits, the remainder of this paper will center primarily around the results attained since the various limits became effective. First of all, the photofluorographic units were for the most part eliminated from use. The primary reason for this was that mass screening for tuberculosis became medically unacceptable. Federal agencies, especially the U.S. Public Health Service, and various States promoted this decline in mass screening because the benefit of mass screening was not worth the risk incurred. However, the few remaining facilities using photofluorographic machines in the State are, to the best of our knowledge, exposing patients below our mandatory limit.

Results of the dental bitewing exposures over the past 3 years indicate a reduction in patient exposure. In 1972, the 75 percentile level was at 1,000 mR per radiograph. In 1973, the year the regulation became effective, the 75 percentile level dropped to approximately 800 mR per exposure. In 1974, the level was again reduced to roughly 600 mR and in 1975, the 75 percentile level was approximately 500 mR per exposure (Fig. 1). Therefore, in 3 years, the 75 percentile level has been decreased by a factor of two.

A comparison of the distribution of dental bitewing exposure measurements prior to the effective date of the dental regulation (1972) with the most recent annual measurement (1975) is shown in figure 2. It is especially important to note that the most frequent exposure measurement is below 500 mR. A decrease in the number of exposures above 1,000 mR is also evident. We hope to accomplish our goal by eliminating all exposures above 1,000 mR within the next couple of years.

Figure 3 summarizes the annual average exposure for dental bitewing examinations. The average exposure is somewhat misleading since the data was skewed to the right, which increases the average exposure measurement. However, by reducing the high exposures, the annual average exposure has decreased since 1972. In 1973, a 2-percent reduction was evident over the 1972 baseline year.

In 1974, a 19-percent decrease was noted over 1972. In 1975, a 31-percent decrease was obtained and in 1976, a 36-percent decrease was evident in data for the first quarter of the calendar year. These percentage reductions become significant when calculating the number of exposures per week by the total number of dental facilities located within the State.

Within the past 3 years, in response to this regulatory effort, we have received positive support for the exposure limit criterion from numerous dentists and professional societies. Many dentists have not only complied with the exposure reduction but have also indicated to us that their radiographs have been improved significantly. All the facilities which exceeded the exposure limit were able to reduce their exposure by either using a higher speed dental film, or by altering their film processing to an adequate time - temperature method, and adjusting their technique factors. We have not received any adverse reaction from licensed practitioners other than those few who seem to always oppose any and all regulatory action involving their practice. However, they do not argue with the exposure limit approach to reduce unnecessary patient exposure. We have found that our greatest task is to educate the practitioner and demonstrate to him that he can achieve a high quality radiograph and yet reduce the incident exposure to his patients by a significant factor.

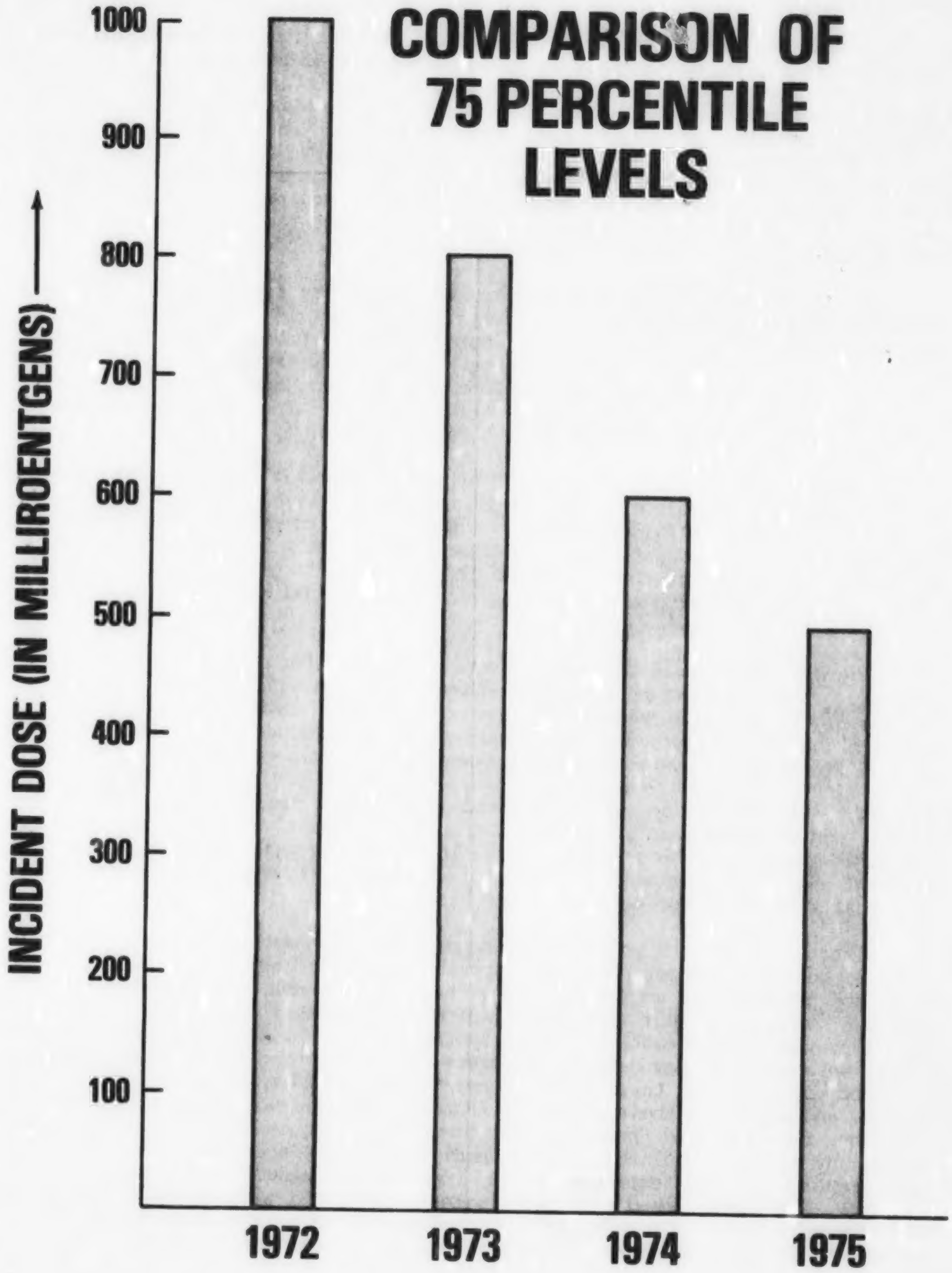
COMPARISON OF 75 PERCENTILE LEVELS
INCIDENT DOSE (IN MILLIROENTGENS) →
1000
900
800
700
600
500
400
300
200
100
1972
1973
1974
1975

Figure 1.

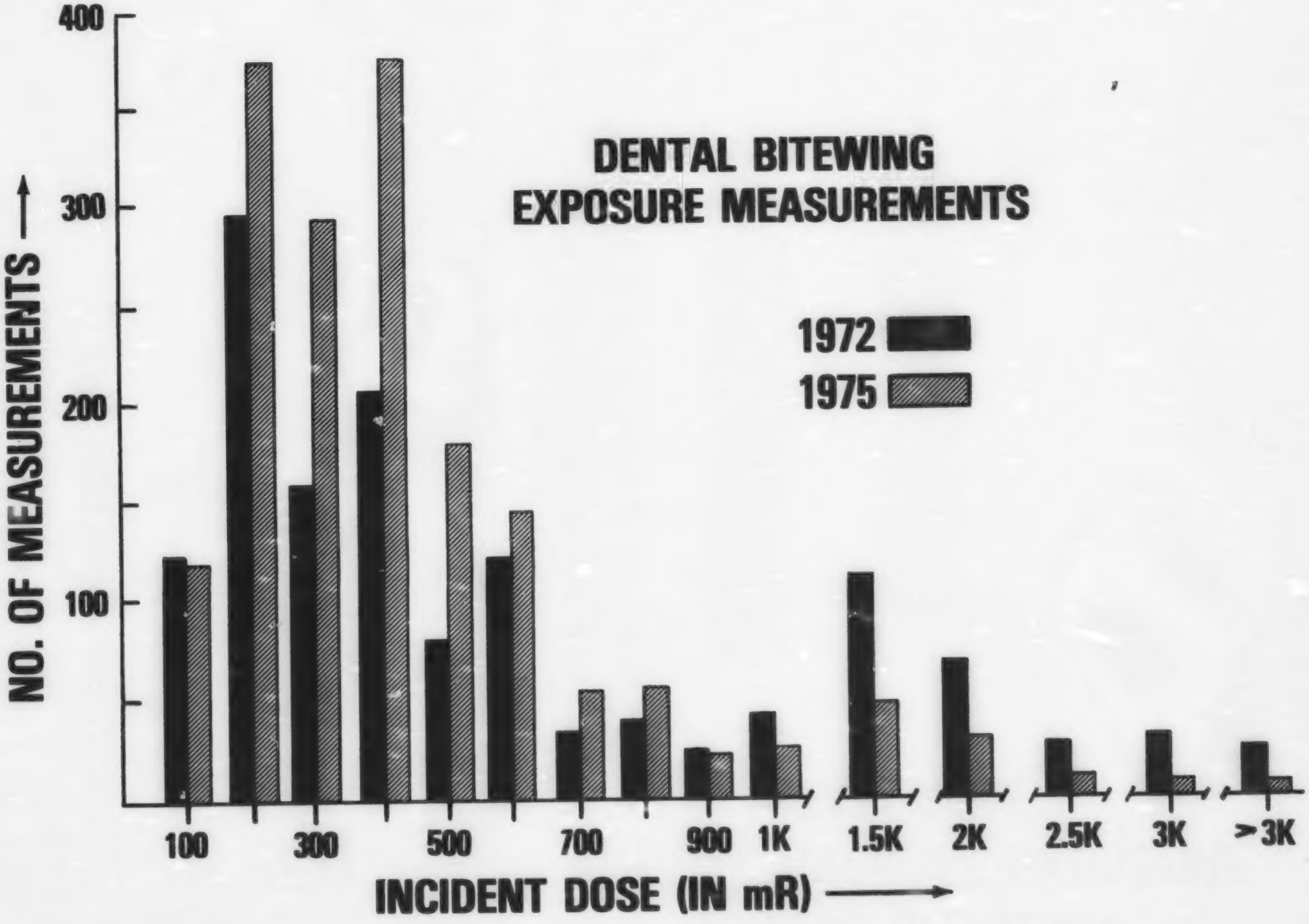
DENTAL BITEWING
EXPOSURE MEASUREMENTS
1972
1975
NO. OF MEASUREMENTS →
400
300
200
100
100
300
500
700
900
1K
1.5K
2K
2.5K
3K
>3K
INCIDENT DOSE (IN mR) →

Figure 2.

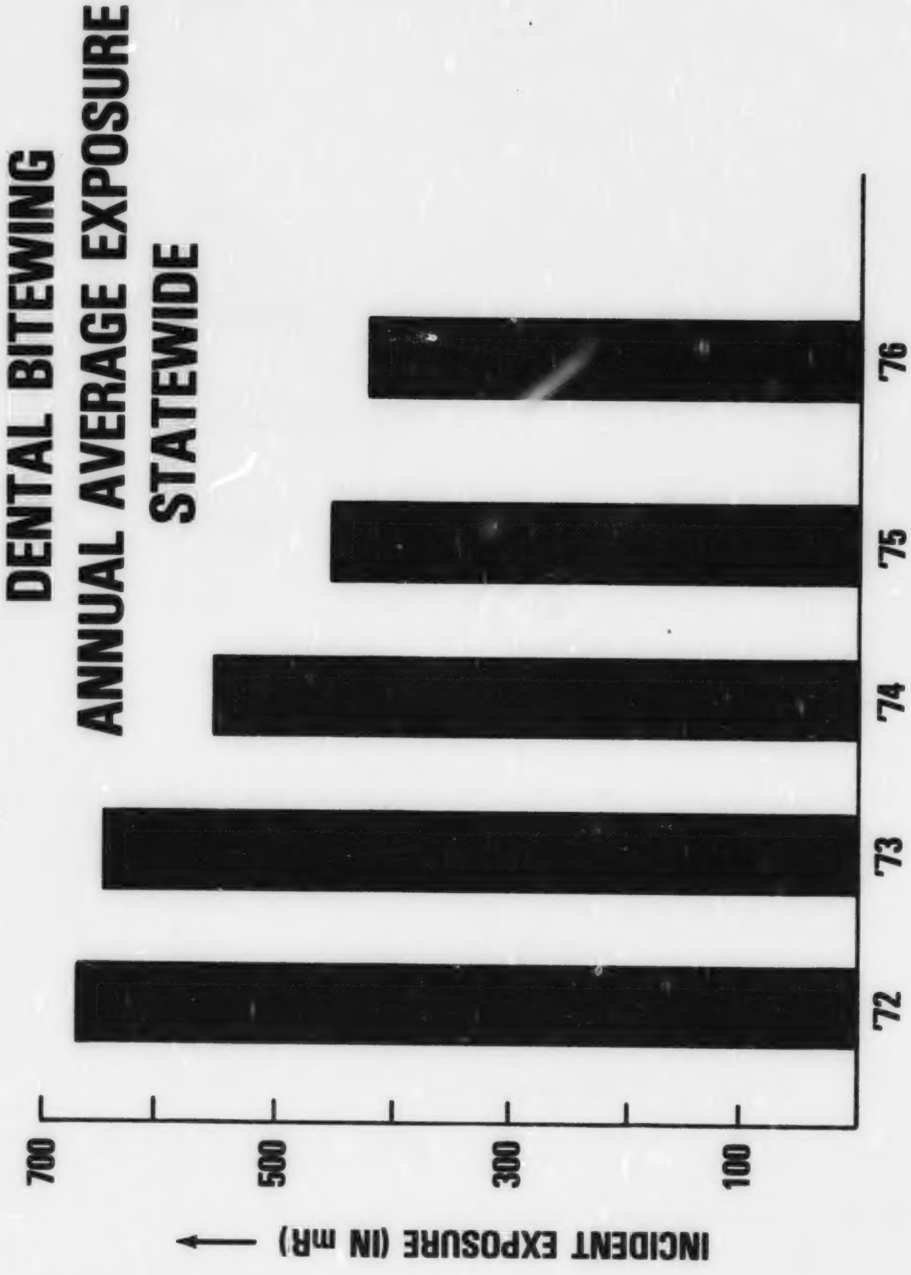
DENTAL BITEWING
ANNUAL AVERAGE EXPOSURE
STATEWIDE
INCIDENT EXPOSURE (IN mR) ⟶
700
500
300
100
'72
'73
'74
'75
'76

Figure 3.

We are not aware of any dentist who has had to purchase a new x-ray unit in order to comply with our limits. Even the low 50 kVp units are adequate if the procedural techniques are refined and properly followed. This approach does not entail any economic hardship on the user . . . just some education to improve radiograph techniques and procedures. Generally, we have found that the younger dental practitioners meet our exposure criteria upon initial inspection and are quite receptive to our exposure limit approach. Generally, major resistance to the regulation has come from the older practitioners. Compliance has, however, been achieved without undue difficulty. We just make them an offer they can't refuse.

A summary evaluation of the medical exposure limits presents results similar to those of the dental exposure evaluation. However, the means toward the end are different. Whereas the major factor in complying with the dental limits was the use of high speed film and/or utilizing proper film development, the medical exposures that exceed the limit are primarily reduced by increasing kVp and reducing mAs accordingly. Approximately 70 percent of the medical machines exceeding the limits were converted by this method. The remaining 30 percent represents a combination of adding filtration in the direct beam of the machine and/or using higher speed film or higher speed fluorescent screens. Film processing is normally uniform, since automatic processors are routinely used except for the private office type facilities.

I would now like to give you a firsthand look at the specific medical x-ray examinations relevant to our exposure limits. Figure 4 indicates the 75 percentile levels for AP Abdomen exposures from 1971 to the present. When the limit was established, the 75 percentile level was 500 mR/radiograph. Today, we are approaching 400 mR/radiograph. The annual average exposure has decreased each year since 1973 and is currently at the lowest point since we initiated this data collection.

Figure 5 shows the 75 percentile levels for AP Cervical Spine since 1971. Note that the level has decreased each year. As of this year, the 75 percentile level has decreased 20 mR/radiograph over the initial limit of 150 mR/radiograph. The annual average exposure has also been reduced significantly since 1972.

The Lateral Lumber Spine 75 percentile levels are shown in figure 6. Note that the level has decreased since our initial limit of 1400 mR/radiograph. The annual average exposure is not as straightforward as with the previous exams. Data collected in 1975 indicate an increase over the preceding year. This could be attributed to the fact that many high exposures might have been located and identified within the year, thus causing an increase in the overall annual average exposure level.

The final analysis and evaluation of the medical examinations consists of the PA Skull exam. The 75 percentile level has remained rather constant over the evaluation period. However, the annual average exposure indicates a slight reduction each year since 1972. In 1972, the annual average exposure was 264 mR/radiograph and has decreased steadily to the present status of 238 mR/radiograph.

These statistics for the four medical exams were derived from roughly 12,000 individual exposure measurements. I think it is important to note that the medical exposure measurements were conducted by using a standardized reference point. The radiation measurement device (LED) was placed directly on the x-ray tabletop also including back-scatter radiation as part of the total

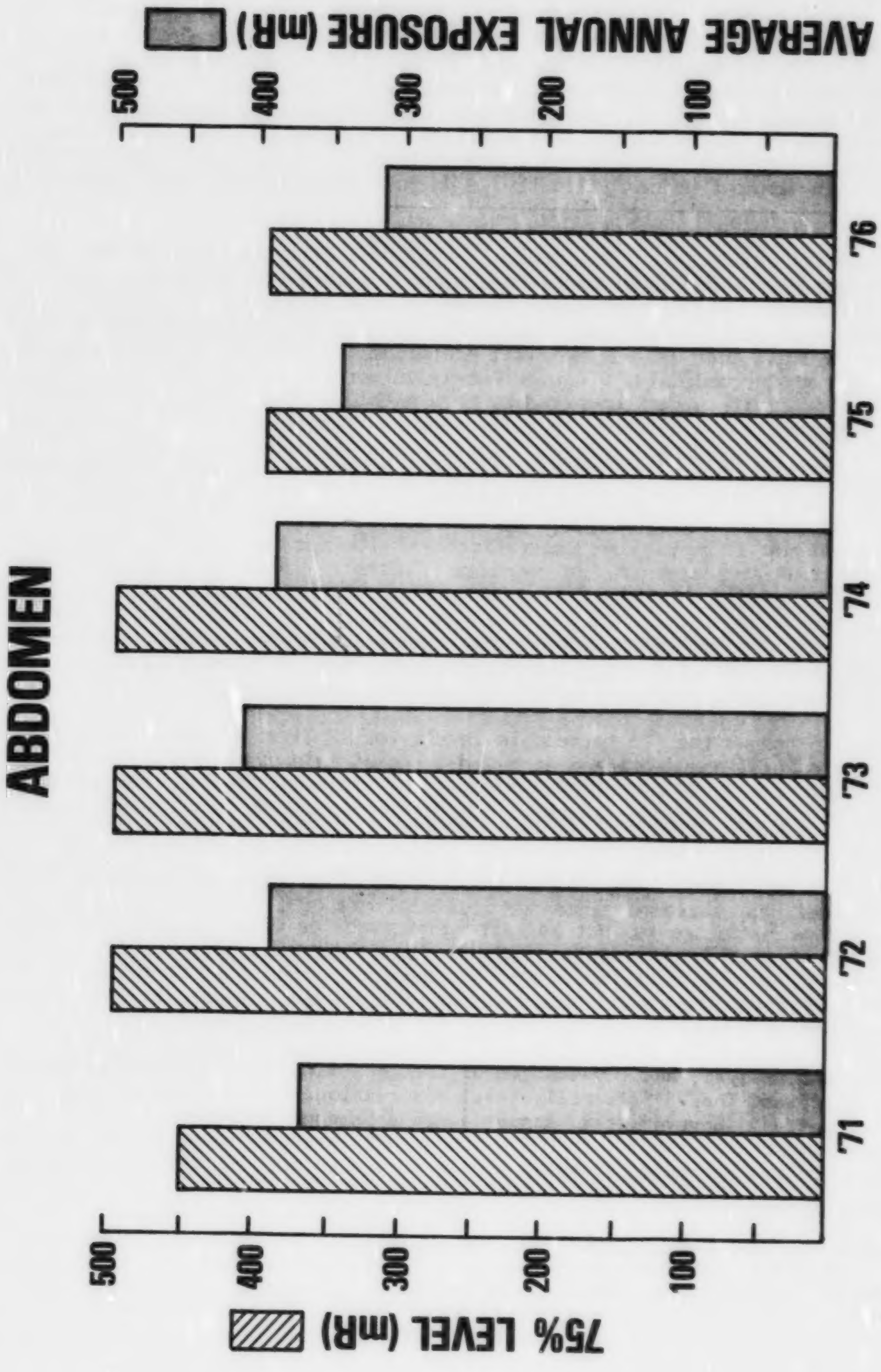
ABDOMEN
AVERAGE ANNUAL EXPOSURE (mR)
75% LEVEL (mR)
500
400
300
200
100
'71
'72
'73
'74
'75
'76

Figure 4.

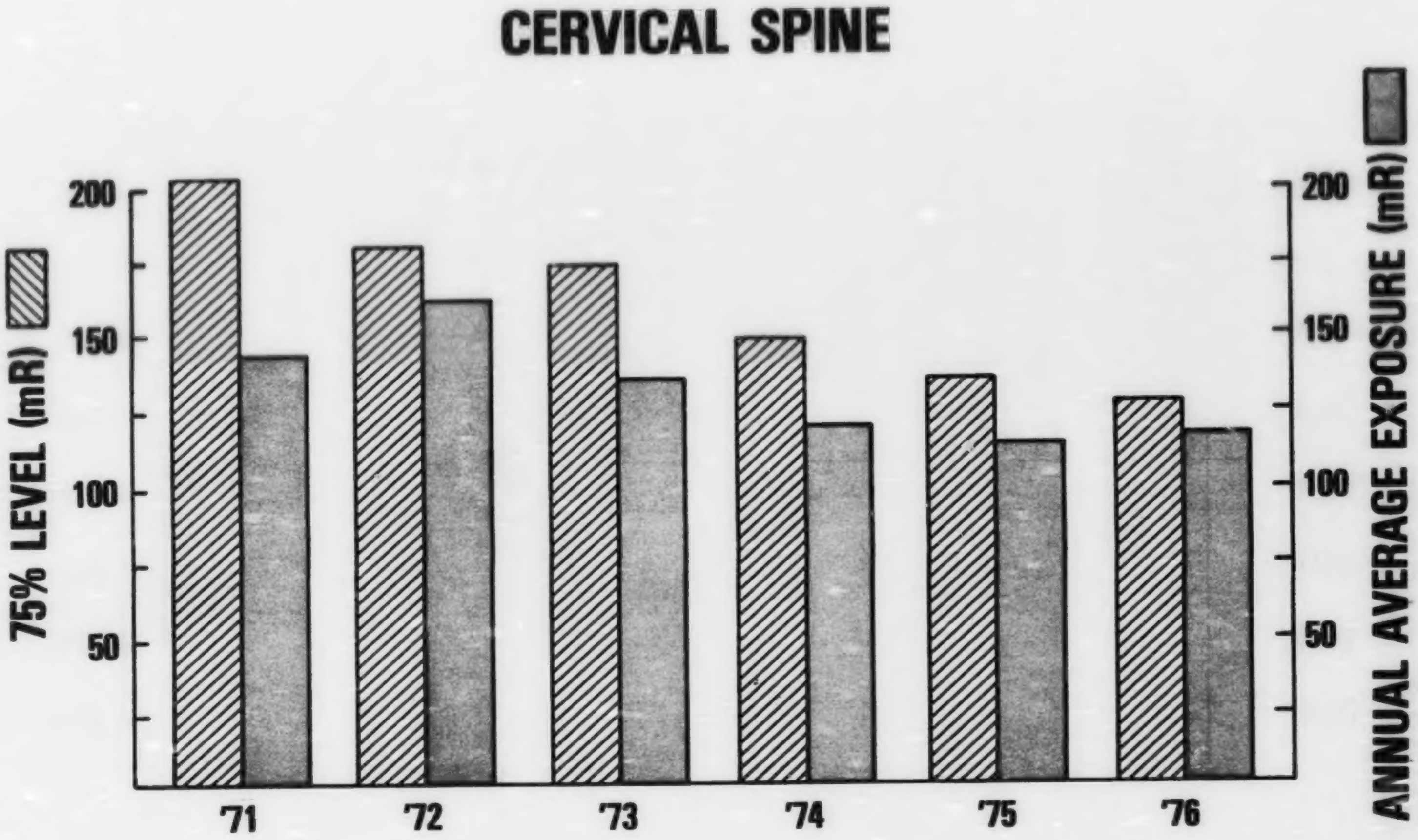
CERVICAL SPINE
75% LEVEL (mR) ▨
ANNUAL AVERAGE EXPOSURE (mR) ▩
200
150
100
50
'71
'72
'73
'74
'75
'76

Figure 5.

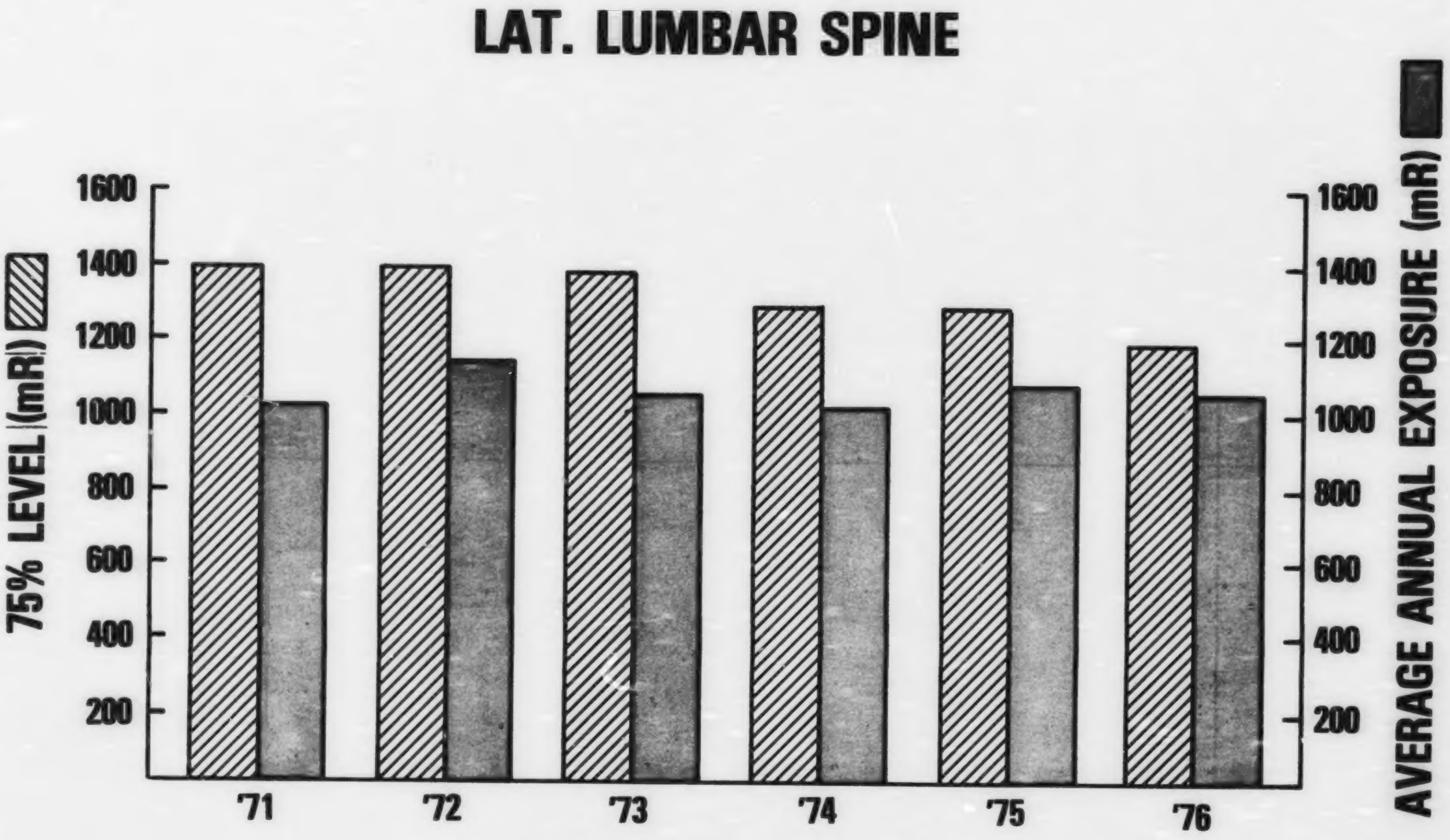
LAT. LUMBAR SPINE
75% LEVEL (mR) ▨
AVERAGE ANNUAL EXPOSURE (mR) ■
1600
1400
1200
1000
800
600
400
200
'71
'72
'73
'74
'75
'76

Figure 6.

exposure. Therefore, it should be recognized that our measurements do NOT reflect actual incident exposure to an average sized adult patient. However, by standardizing the measurement procedure, we have not altered the geometric factors.

The dental bitewing exposure measurements do reflect incident exposure to the patient since the measurement is taken at the end of the position-indicating-device (P.I.D.) and a rice-bag phantom is used for facial simulation.

In conclusion, we feel we have made continued progress with our exposure limit philosophy. Again we stress the importance of educating the radiation users which is paramount in the exposure limit concept. We do not wish to imply that the concept is the "all perfect" method to reduce patient exposure but we can state that a regulatory approach of this type does seem to have a direct impact on reducing patient exposure, which is the name of the game. We anticipate continued cooperation with the dental and medical professions and a continued reduction in patient exposure.

DISCUSSION

DR. BROWN: Let me applaud Illinois. When this program was first mentioned, we created quite a file from Illinois who were "viewing with alarm" this new enterprise.

Let me state for the record I have nothing in my files since the implementation of this program that there has been any compromise in patient care from any radiologist in the State of Illinois. That means that the program has been administered with care and speaks for itself.

Second, the matter of the chest x rays. In the radiological literature for at least 30 years, every radiologist who has studied this has come to the same conclusion you heard this morning. The answers are not so simplistic as they are represented, however. Before you indict admission hospital x rays, you have to examine how many patients are going to get an x ray anyway at some point in their hospitalization. Then you are beginning to talk about at what point do you want to get the x ray. It really is not that simplistic; otherwise it would have been answered a long time ago.

If you have interest in these kinds of problems, I think you are going to have to go into them in much greater depths than you heard this morning.

Third, is the area of credentialing. Radiologists in general strongly endorse your efforts in credentialing as a matter of doctrine. I think you would find that they would agree not to employ, or to relate to other than credentialed operators.

With those three comments, I think you have allies not adversaries to applaud your efforts; however, again, the matter of credentialing is not at that level. The matter of credentialing is whether you are prepared to create a group of independent expert operators for the nonradiologist's machines. That is where you really begin to get into problems; not in this relationship with radiologists.

Again, I compliment Illinois; God's speed; may the program turn out to be a national one.

EPA'S FEDERAL GUIDANCE ON MEDICAL X RAY

James E. Martin
Deputy Director, Criteria and Standards Division
Office of Radiation Programs, EPA

There are many ways I can talk about the area of medical radiation in this the first EPA presentation to this group on our program in this area. I am sure there are some people here who probably would prefer that I not talk about it at all. I have chosen to discuss our program from three basic standpoints: (1) what we see as our responsibility under the Federal Radiation Guidance authority; (2) how we have gone about the program; and (3) what we have accomplished so far.

As the States know better, perhaps, than we, you get your license or your directive to do certain things by appropriate statute. The Federal Government operates according to the United States Code. If you go to that part of the Code entitled "The Public Health and Welfare," Title 42, Section 2021 h, you find the following language: "The Administrator shall advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance to all Federal agencies in the formulation of radiation standards and in the development and execution of programs of cooperation with the States."

This basic authority was established in 1959, first by Executive Order, and second by the Congress passing Public Law 86-373, which provided a statutory basis. Several Federal agencies have regulatory programs for specific radiation sources, but every Federal regulation in existence today is consistent with the Federal Radiation Guides issued under this authority. The basic difference in the authority today from its inception in 1959, is that the Administrator of the Environmental Protection Agency alone now carries out what a seven-member council used to carry out.

Pursuant to this basic authority, the Administrator of EPA wrote to the heads of Federal departments in the summer of 1974 asking them to be represented on an Interagency Working Group on Medical Radiation to examine the use of medical radiation in Federal facilities in order to develop appropriate guides. This working group met first in August 1974; they met again in September and November of 1974 and concluded that Federal guidance was needed for Federal activities in this area. The working group determined that the activity should be directed primarily at the prescription of x rays and the techniques of performing them rather than equipment, which was being actively regulated by the Food and Drug Administration. In addition, they determined that subcommittees should be formed to examine the prescription and technique areas by drawing extensively on expertise in the Federal sector and other expertise to develop recommendations for consideration by the interagency working group for eventual development into Federal Radiation Guides.

The subcommittees used available knowledge to develop recommendations for guidance appropriate for use in Federal health care activities. As most of you know, because we sent you copies, the background report from the Subcommittee on Prescription of Exposure to X Rays (SPEX) was announced in the March 12, 1976 FEDERAL REGISTER. We would very much welcome the opportunity to reflect the expertise represented by people in the States and anybody else in this audience, with respect to the soundness of these recommendations. The interagency working group and its subcommittees would certainly be able to use such comments in its deliberations on where to go with those recommendations.

The other subcommittee on technique is nearing completion of the final draft of its report for in-house review. Very briefly, since you have not seen this report, it mainly considers broad recommendations which address the qualifications of those who operate x-ray machines, the need for quality assurance programs, the responsibilities of technologists in working with patients, and exposure guidelines for selected standard routine examinations.

The guidelines have been well accepted by all the military services. Before the services actually decided on the exposure guidelines, they did something that is fairly important, and it is certainly manageable in the Federal health care sector. They examined their own NEXT data extensively, and then went to their facilitites to see if they could get exposures for their activities below the third quartile of the NEXT data. They found that they could; so the exposure guides, at this point, look like they are going to be in the guides, and that they will be at the third quartile of the NEXT data.

Why have we developed guidance for medical radiation? Many assume that the FRC excluded medical radiation in its guides. Actually, they did not. The first recommendation that was made in the 1960 guides approved by the President is that no radiation exposure be permitted without commensurate benefit. The second recommendation recommended that exposures be kept as low as practicable. The third recommendation established numerical guides for population exposure and occupational radiation exposure. In the footnotes to those numerical guides, it is stated that the numerical guides do not apply to medical radiation or naturally occurring background radiation; that is the only place that medical radiation is excluded in those guidelines. So the broad guidance, principally the recommendations regarding no exposure without commensurate benefit and low as practicable exposure already apply to medical radiation.

As most of you know, the Federal Radiation Council had several activities underway to reexamine the guides when the FRC function was transferred to EPA. An interagency working group was looking at the exposure to the population from all sources, and of course they found that the largest exposure from manmade activities was medical radiation. They quantified these exposures for average individuals. The second major effort was to commission the NAS-BEIR committee study which was completed in EPA. The BEIR Committee concluded that more than 90 percent of the manmade radiation exposure was from medical radiation and recommended that it could be reduced perhaps as much as 50 percent by improvements in equipment, technique, and elimination of mass screening programs.

I bring this up mainly to show that the evolution of events in this area basically required Federal guidance. The authority was there; the studies were being done; and the recommendations were coming out. It was just a matter of time before the Federal Radiation Council got around to that very large and important source of exposure of the population. With this broad authority, and working with Federal agencies, EPA thought that perhaps within the Federal health care sector - not subject to some of the pressures and problems existing in private medicine - we could lend assistance to the efforts of all the groups that are working to reduce unnecessary radiation exposure to the patient. Everything that we have done has been with this in mind; we want to be a cooperative adjunct to existing activities in both the States and the Federal Government to contribute whatever we can to reduce unnecessary medical radiation. I would say to the States, if there is any way that we can use the Federal guidance authority to help your programs, we would be glad to try.

Many of you, perhaps, wonder about the relationship between EPA and BRH on this problem. Let me tell you my feeling. There are many things that the Bureau of Radiological Health can and does do that we cannot. We, on the other hand, because of this extensive authority, can do a few important things that they cannot. We have not undertaken to develop any new program to develop information that the Bureau has underway.

We do, however, bring existing information together and act on it within our basic responsibility in order to work with the Federal agencies to set the basic guides for Federal agencies. To that extent, I think we can do something that they cannot do. Their voluntary guideline approach is a very valuable one, and it is used in these efforts. The guideline on gonad shielding, for example, is being included lock, stock, and barrel in the guidance on technique. One of the things we did on equipment was ask Federal agencies to set an example by using the best equipment available; equipment that conforms to FDA standards. So we made a recommendation in the SPEX report that as soon as practicable, Federal agencies should have equipment that meets the Federal equipment performance standards, irrespective of all the things that they could do to put off meeting that standard. And in the interim, they should meet the recommendations in Part F of the Conference's Suggested State Regulations for the Control of Radiation. To that extent, we hope that will make a difference. It is another example of our using information that already exists.

DISCUSSION

MR. STOCK: I would like to know, for the record, on this "orange" book, did you, in fact, converse with the Bureau of Radiological Health? And one 8-second comment on Dr. Brown's paper, if the radiologists are so all hep to get one of these radiologists licensing bills, how come they killed one, effectively, in Indiana and West Virginia this year?

DR. MARTIN: Yes, the report was developed with at least four people from the Department of Health, Education, and Welfare sitting on the subcommittee. Not all of them were there at all times, but the Chief of Radiology of the National Institutes of Health was on the subcommittee and endorsed it from his point of view. Dr. William Cole, from the Bureau of Radiological Health, was a consultant to the subcommittee, because there were some interdepartmental problems. Dr. Cole and two other representatives from the Bureau of Radiological Health were fully aware of everything that transpired in that subcommittee's meetings. They saw every draft of the report, and made substantial comments and inputs that affected revisions of the report.

MINNESOTA'S SCREENING REGULATIONS

Alice Dolezal
Section of Radiation Control
Minnesota Department of Health

An area that has received considerable risk/benefit evaluation in recent years is x-ray screening. During the years of high tuberculosis prevalence the value of mass x-ray screening was unquestioned. The vigor of 30 years ago produced not only improved availability of x-ray screening but also the public sentiment that all is well when each person gets an annual chest x ray.

Over the years the discovery of decreasing numbers of new TB cases induced Minnesota to reassess the benefits and necessity of the extensive tuberculosis screening program. The State-wide x-ray screening program with the State-owned 70-mm photographic units was discontinued in 1953. However, county and facility screening programs continued.

In 1967 the Minnesota Health Department began to evaluate and question the productivity of the tuberculosis x-ray screening program at State institutions and hospitals. Gradually, routine screening by the State-owned mobile unit was abolished, and tuberculin testing was substituted for annual chest x-ray radiographs in most State institutions. So in 1972, when the Assistant Secretary for Health and Scientific Affairs announced the Department of Health, Education, and Welfare policy statement on mass x-ray screening, Minnesota regarded this as a reinforcement of its own policy and views on mass x-ray screening and an incentive to carry through on the program of eliminating mass x-ray screening for the general population.

The radiation exposure per film from photofluorograph units far exceeds the radiation exposure to film from conventional x-ray units. This is particularly true of old PFG units. Thus as a means to reduce unnecessary radiation exposure, a regulation was proposed which would prohibit the use of photofluorographic x-ray machines for the purpose of screening of human beings for health conditions. Screening was defined as the testing of human beings or human population groups for the detection of health conditions when such tests are not specifically and individually ordered by a licensed practitioner authorized to order such tests for the purpose of diagnosis or treatment or as part of a physical examination being conducted by a licensed practitioner.

A public hearing was held in May 1974 to obtain public comment on the proposed regulation. Several speakers from the Minnesota Medical Society and the public spoke in favor of the proposed regulation. However, representatives from the Old Delft Corporation, who in their testimony stated that the company "almost has a monopoly on this type of equipment...," objected to the regulation because one specific type of x-ray machine was singled out and its use prohibited in screening. The regulation was branded as discriminatory.

Testimony from the hearing was evaluated and a reassessment was made of current x-ray screening practices in Minnesota. The Minnesota Health Department had discussed x-ray screening with the State TB Association and they in turn talked with county TB centers. Only occasional mass x-ray screening was being conducted by the tuberculosis associations at the time of the hearing. However, as the State and county screening programs decreased, companies with privately owned mobile vans began to sell their services to industries and cooperatives. In some cases the screening was restricted to chest x-ray radiographs, but multiphasic screening was now being introduced. In addition to chest x-ray radiographs, maxillo-facial x rays are routinely administered during screening, with the possibility of additional projections being added to the screening.

When the company that sells multiphasic screening services, including chest x rays and maxillo-facial x rays, applied for registration in the State, we discussed this concept of screening with them. They felt that they should be free to take x rays as long as they complied with the letter of the law for the Health Department regulations. They were complying with existing Health Department regulations at the time; however, the Health Department medical and dental representatives were informed of the screening. They in turn approached their respective associations. The Dental Board of Examiners held a special meeting to decide if administration of the maxillo-facila x rays are in violation of the State Dental Code. The meeting was attended by representatives of the Minnesota Dental Association; Minnesota Health Department, Dental Section; and American Health Profiles, Incorporated, the company involved. The Dental Board of Examiners concluded that the administration and diagnosis of the maxillo-facial x rays as performed by the company is a violation of the State Dental Code. Rather than have an injunction imposed upon them, the company voluntarily withdrew from performing that projection during screening. To our knowledge the company has not conducted screening in Minnesota since that meeting.

At the time of the meeting with the Dental Board of Examiners another proposed regulation on x-ray screening was being prepared by the Minnesota Department of Health. It was the decision of the Minnesota Board of Health that a regulation should be written proposing that all x-ray screening be prohibited without prior written approval of the Board. This regulation would apply to all types of x-ray machines, not just to photofluorographic units and to all types of x-ray screening, not just chest x rays. The proposed regulation included the requirement to submit the information requested on the screening purpose and procedure. For example: when and where the screening will be performed, description of the type of screening, age distribution of the population to be screened, the amount of x-ray exposure to which individuals will be subjected (a limit of 50 mR per radiograph for chest PA views is required), and the health reasons, benefits, or emergency that justifies the radiation exposure to the individuals. Information is also required on obtaining the results from the screening; who will interpret the film, to whom will the results be sent, where will the x-ray film be filed, who will have access to it, by what method will the persons screened be informed of the results.

After considering all of the information submitted, the Board will give written approval if the screening is judged to be a justified public health measure and the benefit derived from the proposed screening will outweight the potential detriment of x-ray exposure. The equipment and screening program are subject to inspection by the Health Department. If a radiation hazard is found, the Health Department may terminate the screening until the hazardous conditions are corrected.

A public hearing was held on the proposed regulation on October 24, 1975, to obtain comments on the regulation. Dr. William Cole from the Bureau of Radiological Health in Rockville testified in favor of the regulation. Emphasis was placed on the importance of reducing chest x-ray surveys to the general population. An American Health Profiles company representative also testified in general accord with the regulation. It remains to be seen to what extent there is agreement when the company submits an application for screening.

Written comments were also submitted during the hearing and during the 20-day comment period. After consideration of the testimony and comments, some changes were made in the proposed regulation. Several wording changes were made for clarification. A somewhat more significant alteration of the proposed regulation was made in the definition of screening so as to exclude certain areas of research. Although no specific wording had previously been directed to include research in the definition of screening, research was not specifially excluded from the regulation. Two of the large hospitals in Minnesota at which extensive research is performed stated that the amount of time and paperwork required to comply with the State regulation would be considerable. It was felt that in some instances this would make it difficult to also meet grant schedules imposed by HEW and other Federal agencies financing research projects. In addition, these facilities expressed the opinion that the safeguards written into the ethics code and the evaluation by the Federal human ethics committees were sufficient. State evaluation would not add safety but rather prove to be a deterrent to some research.

Considerable discussion ensued with the Board of Health, the Health Department, and the facilities that expressed concern. While screening conducted during research at facilities with human ethics committees and certain educational institutions probably do not provide a hazard to the public, concern was expressed regarding institutions and groups that are not subject to thorough internal review or outside regulation. A compromise was reached by modifying the definition of screening to exclude research protocols utilizing x-ray procedures when such protocols are part of research projects (1) sponsored or financed by agencies of the Federal Government, (2) conducted by educational institutions training practitioners of the healing arts, or (3) conducted in hospitals, when such research is authorized by or under control of the governing body of that hospital. With the modified definition incorporated, the Board of Health approved the proposed regulation. In Minnesota, for a regulation to be final and have the effect of law, it must be approved by the Minnesota Attorney General. A representative from the Attorney General's office provides legal counsel to the Board of Health. Following Board of Health approval of the x-ray screening regulation, the Attorney General's representative to the Health Department is studying the regulation to determine if another hearing is required or if any other modification is necessary for legal purposes. Currently, the regulation is in the office of the Attorney General's representative to the Board of Health. If, in his judgment, no further action is required, the proposed regulation will be sent to the Minnesota Attorney General for approval. If he concurs that no further action is necessary, the regulation will be approved.

This is the status of Minnesota's screening regulations. The effectiveness of the regulation will be determined when screening applications are made. As more States adopt screening regulations, enforcement of the regulations on companies that operate in many States will be easier and the attitudes toward screening will change.

RADIOLOGY QUALITY ASSURANCE OVERVIEW

William S. Properzio, Ph.D.
Division of Training and Medical Applications
Bureau of Radiological Health, FDA

Quality Assurance seems to be the catchword of our time. Any of us who has purchased a new car recently has inevitably proceeded to question the adequacy of the manufacturer's quality assurance program that allowed a vehicle like the one we obtained to ever leave the factory.

Our interest here is the application of quality assurance in areas related to medical radiation exposure. From a technical detail basis, the problems in medical radiation exposure are not comparable to those associated with the auto industry but the input of quality assurance is needed in both areas for the same reason, namely, to assure that the desired goal of producing a product of consistent quality is achieved. The Bureau of Radiological Health is currently active in the development and implementation of quality assurance in diagnostic x ray and nuclear medicine. Some of the nuclear medicine activities will be discussed in two subsequent papers in this session by Mr. Richard Van Tuinen and Dr. Peter Paras. I will therefore restrict my remarks to diagnostic x ray.

What is quality assurance as applied to diagnostic radiology? One definition that has been suggested is as follows:

> Quality assurance: Those maintenance and administrative actions taken to insure that equipment (once manufactured and installed according to regulations) and operators (once trained) continue to perform in such a way as to produce consistent high quality radiographs at minimum patient exposure.

An analysis of this definition suggests that the major responsibility for the conduct of a diagnostic x-ray quality assurance program lies with the medical and dental practitioner and technologist. This, in fact, is the case since, at the present time, only the practitioner can adquately define what constitutes an acceptable "high quality" radiograph and only at the facility level can a day-to-day monitoring program be carried out to identify problems that could adversely affect the ability to produce high quality radiographs.

Although the primary responsibility for implementation of quality assurance is at the user level, local, State, and Federal radiological health agencies have a major responsibility for promoting and establishing effective quality assurance programs. Health agencies should establish user requirements for the setup and operation of quality assurance programs. In many cases health agency personnel must be in a position to provide technical assistance to the user with regard to the establishing of a program and be able to monitor its effectiveness.

Evidence of the need for quality assurance in diagnostic radiology is unquestioned. The published results from the first round of chest films obtained in the pneumoconiosis program, operated by the National Institute of Occupational Safety and Health (NIOSH), reported extremely high numbers of undiagnostic films. Trout et al. *(1)* reported that although only 3 percent of the radiographs taken in the "black lung" survey were rejected by the expert review radiologists (the so called B and C readers), 44 percent of the facilities in the program had more than 10 percent of their radiographs rejected and in one large volume facility the rejection rate reached 40 percent. Dr. Felson, a member of the NIOSH panel of radiology consultants, stated that half the films taken in mining communities by non-radiologists were of unreadable quality *(2)*. NIOSH has instituted a number of corrective actions including such quality assurance measures as the requirement that all facilities wishing to participate submit radiographs obtained with the Trout test phantom for evaluation *(3)*.

An evaluation of rejection rates for dental films that were submitted to the Pennsylvania Blue Shield program for pre-treatment authorization is soon to be published by Beideman, Johnson, and Alcox *(4)*. In this study 1000 cases which included 412 full- and 588 partial-mouth series, were evaluated. Their findings indicate that only 35 percent of the full-mouth and 15 percent of the partial-mouth series submitted were considered fully satisfactory. The films were evaluated on the basis of 12 criteria. Poor processing was identified as a problem in 12.4 percent and 5.6 percent respectively of the full- and partial-mouth series. Improper density was a problem in 10 to 13 percent of the cases. These sources of error could be reduced or eliminated through the institution of properly run quality assurance programs.

Data from the Nationwide Evaluation of X-Ray Trends (NEXT) surveys *(5)* show variation in exposures that cannot be explained solely in terms of the difference in films and/or film screen types in current use. Poor technique and inadequate processing are suspected; here again the goal of reducing these variations can most effectively be achieved through quality assurance.

What should be the commitment of a regulatory program to diagnostic quality assurance? At the Federal level, the Bureau of Radiological Health will be announcing via the FEDERAL REGISTER in the next few days its intent to develop quality assurance recommendations. The essence of a future recommendation at the Federal level might be a general statement that any facility performing diagnostic radiology on humans should have an organized and operational quality assurance program. The content and emphasis of such a facility run quality assurance program would necessarily vary from facility to facility, based primarily on the type of practice and/or procedures performed. For example, a dental quality assurance program would differ from the approach taken in a medical facility. Programs having different emphasis should also be set up for the various classifications of medical practice. A large research or teaching hospital which performs a large number of examinations and often has a medical physicist can institute a different level program from that to be expected in a small community hospital or clinic where a technologist may be responsible for setup and operation of a program.

At the present time one of the needs of individuals in the medical community is detailed information on the steps that they can take to improve image quality in diagnostic procedures. We hope that the quality assurance recommendation and backup technical details will provide this information. The States will also be able to utilize the Federal recommendation in their efforts to encourage radiology facilities to initiate quality assurance programs.

The Bureau's quality assurance recommendations will be developed publicly with heavy reliance on outside input to its detailed content and overall approach. For example, the open comment period for an Advance Notice of Proposed Recommendation (ANPR) is usually 30-60 days. We have asked for and have been granted an extension in this area to 6 months. We hope that this approach will allow time for adequate input and that the recommendation is sound and can be implemented in a cost effective manner.

The effective utilization of diagnostic quality assurance techniques can only be achieved if a number of elements are available. First, there must be a commitment by the facility to establish a program. This commitment may involve the purchase of test equipment and the identification and training of personnel to implement the program. Secondly, facilities must be provided with technical information detailing how to effectively carry out a testing program. This type of information is currently being made available in publications and training programs by various individuals, industry and professional societies. For example, the American Association of Physicists in Medicine with the assistance of the American College of Radiology and the Bureau of Radiological Health will soon be publishing a comprehensive technologist level test method document. State and Federal radiological health personnel who have been actively involved in diagnostic x-ray programs for many years can also be looked upon as a source of expertise in identifying priorities and developing test procedures.

The final element in achieving the goal of effective utilization of quality assurance techniques requires the active involvement of the radiological health program to promote the establishment and utilization of quality assurance test procedures and to monitor their effectiveness.

During the last year a survey was carried out with the help of FDA's Regional Radiological Health Representatives who collected data on the various x-ray survey procedures currently being implemented by the State and local programs. We have now received the data from 44 of these programs. It indicates that the potential for reducing unnecessary x-ray exposure through various quality assurance procedures is already recognized and being carried out in a number of areas. For example, 77 percent of the 44 programs indicated that some aspect of darkroom operation was being included as part of a facility survey. Approximately 50 percent of the programs indicated they looked at some aspect of the operation of automatic processors. On the surface this involvement in automatic processing is encouraging since recent data *(6)* have identified significant variations that often exist in these systems that could lead to poor image quality and increased patient exposure. The disturbing fact identified by the summary was the large variation in survey procedures used. Combinations of at least 10 different factors were looked at in regard to automatic processing. These ranged from those who measured developer, fixer, or dryer temperature, processor cycle time, chemical activity of solutions to those who evaluated the sensitometric performance of the system. Although the need to monitor the performance of automatic processors seems to be recognized, in many cases the survey approach is random. It would be my conclusion that in many cases the survey or measurement procedures used are not effective in identifying a problem or suggesting a potential solution.

With respect to the x-ray equipment, 45 percent of the programs said they checked exposure reproducibility, while 68 percent checked timer accuracy. If this survey gives us a reasonable picture, it suggests that many surveyors do what is easiest or what they feel most comfortable with and not what should be done in a logical priority order. None of the 44 programs reported checking on items relating to image quality, such as film screen contact or grid condition and/or alignment.

Other packaged action programs such as the Dental Exposure Normalization Technique (DENT) may also be an effective way for State and local programs to utilize a quality assurance approach. The results of what can be achieved by this approach are impressive. For example, in the 7 States that have completed both Phase I and Phase II of DENT an average exposure reduction of 252 mR/film for all x-ray units has been obtained. Medical radiography presents a more complex array of problems than does dental radiography. Even though the medical equivalent of DENT does not currently exist and may never be able to be developed into such a succinct package, the potential for reduction of exposure is obvious. An investigative pilot study of a non-regulatory State based approach to quality assurance has been carried out by the Bureau in conjunction with the West Virginia radiological health program. The results of this study are very encouraging and will be discussed by Beattie DeBord in the next paper in this session.

The question of how States might proceed most effectively in a quality assurance oriented approach to reduce unnecessary exposure is presently open for discussion. A number of approaches may be potentially fruitful, such as (a) regulatory requirements for the setup and operation of quality assurance programs by all diagnostic x-ray users, (b) patient exposure limits such as those being used by Illinois that can be used to identify facilities where corrective actions may be necessary, (c) a medically oriented DENT program, (d) specialized action programs geared to a unique problem area, such as mammography. These are but a few options. An answer to the question of how most effectively to proceed in these new areas might best be attacked by a new State/Federal Working Group.

The Bureau of Radiological Health is convinced that a shift to quality assurance action programs will be an effective approach to achieving a significant reduction in unnecessary exposure. We hope that the States will be in position to actively work with us to develop effective State oriented programs.

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RESULTS OF WEST VIRGINIA'S QUALITY ASSURANCE PROJECT

Beattie DeBord
Radiological Health Program
West Virginia State Department of Health

For considerable time, it has been known that a variety of medical x-ray facilities were not consistently producing good quality radiographs. This situation has been dramatically documented for chest examinations through the joint efforts of the National Institute of Occupational Safety and Health (NIOSH) and the American College of Radiology. The NIOSH/ACR pneumoconiosis program involves a system of peer review utilized to evaluate films submitted as a basis of claims for compensation by active coal miners. The project clearly indicates that many films are of unreadable quality.

Similar results have been obtained through a similar program for retired coal miners under the auspices of the Department of Labor. In an effort to discover the reasons for this poor film quality, the Bureau of Radiological Health, in cooperation with the American College of Radiology, agreed to conduct a series of facility quality assurance and surveys. The approval and cooperation of our State radiation control program was obtained for a joint effort in this area. The project became known as the West Virginia Pilot Study, and subsequently became incorporated into the overall DTMA quality assurance effort.

This project served to test the feasibility of a voluntary State radiation control program to assist physicians and hospitals to improve certain aspects of diagnostic radiography through the application of quality assurance techniques. The project involved the promotion of quality assurance at the facility level, the rendering of appropriate assistance to facilities in the process of establishing their own quality assurance program, and the monitoring of established programs in order to determine their effectiveness.

We chose three facilities to visit in May of last year, and fifteen in September. The first three were selected for the purpose of accomplishing three goals. Our first goal was to perform a useful service to the facilities visited. It was our intention that the information contained in the reports be sent to these facilities after our visits and identify any existing equipment problems which could have an impact on the radiographic quality. Second, the visits provided a field test for our quality assurance activities. It was necessary that we have clinical facilities to test their instruments and procedures in order to determine whether they were appropriate for use outside the laboratory; and more important, to determine whether we were measuring those parameters which really affect the practice of radiology. Third, the visit served as a feasibility test for State radiological health programs involved in quality assurance.

We were interested in determining whether it would be practical for States to perform a quality assurance consulting service for radiological facilities as opposed to the traditional regulatory roles. Through the efforts of Mr. Otha Linton, Director of Governmental Relations in the American College of Radiology, we were able to obtain support for the project long before the first surveys. Mr. Linton and the ACR were instrumental in sending explanatory letters to West Virginia Chapters of professional medical societies and key individuals in the State's radiology community. These letters also emphasized that although the individuals conducting the survey were staff members of the Bureau of Radiological Health and our Radiological Health Program, the project was voluntary so far as those requested to participate were concerned. The letters also stressed that there would be no regulatory activities of any kind connected with this project. Without this foreword, I am sure the response to this project would not have been as favorable as it was. Only one facility refused to participate, and this facility was not one of those facilities that we went to and asked if we could come to the facility to do a review, but rather it was one facility that received the letter from the ACR to inform them that we were going to conduct this project and we would like their participation.

At the onset of the project, it was decided that the project should be structured, rather than survey, format. The following parameters were selected for inclusion in the study: kVp accuracy, timer accuracy, exposure linearity, exposure reproducibility, half-value layer, light, x-ray field congruence, SID indicator accuracy, central ray alignment, view box illuminescence, focal spot size, film/screen contact, dark room darkness, sensitometry, and processor temperature and cycle time. The testing methods used for these parameters were discussed at the table clinic, so I will not go into those.

Due to the difficulties entailed in explaining in unambiguous fashion the focal spot size to the first three facilities, it was decided that the focal spot data would continue to be collected, but the results would not be recorded for the remaining facilities. Three new elements were added to the project at this point. They were: (1) a NEXT survey, which is a PA chest, (2) the Trout step wedge test, and (3) a subjective evaluation of selected test films by two outside radiologists. The film evaluators were both "C" readers in the NIOSH pneumoconiosis program. To say the least, I had reservations about asking physicians for films that would be away from their facilities for a period of at least 2 weeks, but we received film from all the remaining 15 facilities.

In the interest of time, the results of the tests will not be discussed; however, this information is available. The data shows that problem areas can be identified by physical tests, and it is also clear that quality assurance activities at the facility level can help minimize or eliminate those difficulties. It is not clear, however, that these physical tests can pinpoint the causes of clinically significant degradations in film response. It was hoped that these tests, in conjunction with radiologists evaluations would serve this purpose. This concept did not turn out to be as simple as hoped.

One problem involved the significant difference of opinion on the part of two highly skilled radiologists, but evaluating the same film with respect to a specific parameter. Another, and perhaps more difficult problem, resulted from the possible use of a different machine--processor combinations for the physical tests than those used to obtain the films selected for evaluation.

Providing direct quality assurance to facilities is an activity with many facets. The interaction between the State and facilities must reflect the size, resources, and specific needs of that facility. This requires that at least two distinct approaches be available for use with respect to targetted facilities.

In the case of large facilities, our role is largely promotional. This involves not only meeting with the appropriate individuals at the facility and discussing the need for, and the advantages of, quality assurance, but also distributing technical material and demonstrating selected quality assurance procedures. At present, we have three large facilities involved. One of these had an ongoing program before we talked to them about quality assurance, and our role there has been largely to advise. This facility estimates that they have saved $38,000 in the first year of quality assurance activities. In another facility, which has a health physicist on the staff, we have demonstrated the quality assurance program, and he and his staff are in process of establishing the program. In the third facility, we have trained a technologist to conduct a quality assurance program. This facility is very close to our office, so we loaned them any equipment that they do not already have.

In the case of some medium and small sized facilities, the assistance is more direct. Such facilities may not have the resources to support a quality assurance program on the scale that could be adopted by larger facilities. They are encouraged and assisted in establishing whatever level of quality assurance activity they can support. At present, we have 74 such facilities involved in our program. These facilities are visited periodically, and our staff does the testing; however, we do not do a complete quality assurance survey at these facilities because of the time involved and the film processing tests that should be done daily.

The data collected and field experience gained during the project are sufficient to allow several conclusions to be drawn; perhaps the most important is that facilities will voluntarily cooperate with State radiation control program personnel in a quality assurance program. And finally, a great deal of enthusiasm has been generated in our State for the project. Hospital personnel are especially interested and have initiated several requests for aid in establishing a quality assurance program.

In the future, certain parts of the quality assurance project will be incorporated into our compliance surveys. This is not to say that we are going to require quality assurance at each facility, but rather we will conduct a limited quality assurance survey at the facility and report any deficiencies to that facility. Based on past experiences, we believe that the facilities will voluntarily correct those deficiences noted.

In conclusion, the radiograph is a primary diagnostic tool in medicine today, and radiography is fundamental in every medical care system; yet diagnostic radiology is the largest contributor of manmade exposure to the population. I believe that quality assurance can produce a better diagnostic radiograph, and at the same time reduce radiation exposure to the patient.

QUALITY ASSURANCE TEACHING PROGRAM FOR NUCLEAR MEDICINE TECHNOLOGISTS

Richard J. Van Tuinen
Nuclear Medicine Laboratory (Cincinnati)
Division of Radioactive Materials and Nuclear Medicine
Bureau of Radiological Health, FDA

Medical users of radioactive materials, like workers in diagnostic roentgenology have need of quality assurance in their daily work. Our application of this concept in nuclear medicine has been those checks or tests which establish day-to-day reproducibility or consistency, whether it be for instruments or for radiopharmaceutical products. Broadly, the nuclear medicine areas we have targeted for development of quality control procedures are imaging instrumentation, radiopharmaceutical products, and in vitro procedures.

Included in the imaging instrumentation group are the two principal imaging devices used in nuclear medicine: the scintillation camera and the rectilinear scanner. In the area of radiopharmaceutical products, as well as general safety and handling techniques for all radionuclides. In the third category is the large area of in vitro testing, and associated radiation counting instruments.

For the first category--imaging instruments, we have emphasized the daily use of qualitative test procedures. The last group of in vitro tests involves the application of more rigorous statistical tests--those that you were probably more familiar with back in the days of measuring fallout.

Our concern about the utilization of quality assurance in nuclear medicine took a quantum leap when we read of a survey conducted by the College of American Pathologists in 1970. Results reported in this survey showed that, of the 560 laboratories using radioactive materials, only 49 maintained a quality assurance program--that is, less than 10 percent. Knowing something about the variances of instrument performance, the procedural requirements for correct radiopharmaceutical preparations, and the overall lower information content of nuclear medicine imaging studies, made us realize that the application of this radiation modality probably was not operating at the minimal exposure level. In a local survey, we found that 5 out of 12 hospitals had no, or less than minimally adequate, quality control checks for their scintillation cameras.

Some of the findings from the survey are shown in figure 1. This is a test of the uniformity of response for the detector field-of-view. The best example of uniformity in our survey is shown in the upper left as No. 11. The three worst are shown as 3, 5, and 9. Of the four cameras, No. 9 was the newest--between 1 and 2 years of age. Camera No. 3 was tested after three of the day s patients were brought back for repeat views, and one patient had a repeat injection. In spite of the ample writings and discussions of quality control, and even regulations and standards, apparently very little of it is effectively reaching the operator.

At about this same time, a similar concern was being expressed by Dr. William Hendee, of the University of Colorado Medical Center. As a consequence, we have collaboratively proposed a series of quality control training programs in the form of workshops designed for nuclear medicine technologists. Each workshop would be limited to a major topic and would involve hands-on experience for each participant. With support from the regional medical programs, the first workshop on quality control for scintillation cameras was developed and presented in the Colorado-Wyoming area, and then on a nationwide basis by the Bureau of Radiological Health.

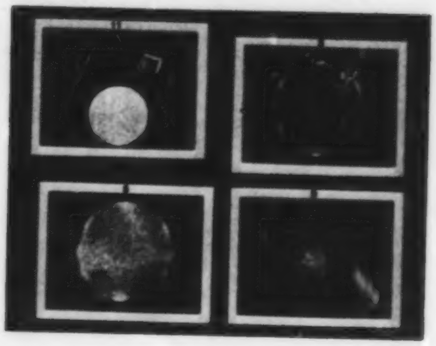

Figure 1. Comparative test of scintillation cameras for the uniformity of detector response.

We selected the scintillation camera first, because of its widespread use for imaging studies in nuclear medicine. A daily quality control procedure for this instrument involves a qualitative check of the reproducibility of at least three of its imaging parameters: uniformity, spatial linearity, and resolving power.

The requirements for quality control testing of the scintillation camera are: a radiation source, a bar phantom, and 15 minutes of time each day. This makes it simple and relatively easy to perform. It has a unique byproduct in that when you verify the reproducibility of the unit, you virtually eliminate the introduction of electronic-induced artifacts that interfere with diagnostic evaluation or that could potentially lead to a misdiagnosis.

The scintillation camera has the unique ability to reproduce the distribution of gamma rays from a patient organ system with comparatively good resolution. The most prevalent detector is a large sodium-iodide crystal, 11 to 16 inches in diameter, and it is viewed by 19 or 37 photomultiplier tubes. The location of the interacting events in the crystal on an X-Y coordinate basis, and an energy determination, are then processed in a complex series of steps before visual representation is obtained. One essential performance parameter is that each area of the detector must be in balance, or in tune, with every other area. Figure 2 shows some examples of detector nonuniformity.

In nuclear medicine, a pathologic process is recognized by the presence or absence in uptake of radioactive material by the organ. Any instrumentation artifacts present will be superimposed into any study conducted in their presence. This is illustrated in figure 3 showing a lung study. As a physician views this, he will compare each of the views, noting any defects in uptake of radioactive material by the organ. The upper two views are overexposed, but not so much as to be of no value. In the two lower views, some defects in uptake would be noted particularly in the mid- and basal-areas and along the lateral margins. These defects in organ uptake of the radioactive material typify what is called a perfusion defect, and their location in this instance is representative of a chronic-type pathologic condition. Without more information, the physician might be tempted to call it just that.

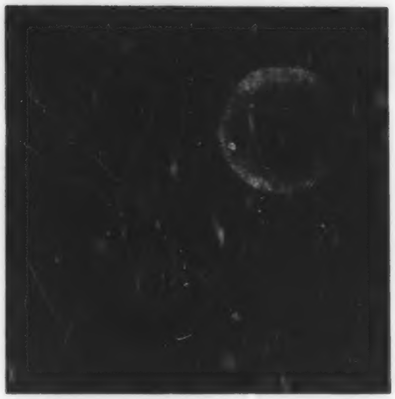

Figure 2. Examples of nonuniformity of detector response for scintillation cameras.

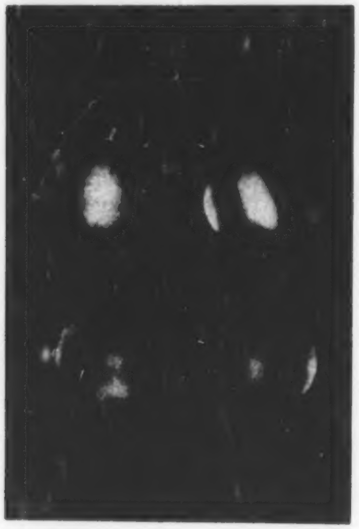

Figure 3. Scintiphotos of a lung scan obtained with ^{99m}Tc-MAA.

However, there is one other explanation for this inhomogeneous distribution and that is instrument artifact. If the physician has a high index of suspicion, and if he has more information available to him, it is likely that after searching for some period of time, he would conclude that the defects are not due to any pathology, but due to variance in instrument performance. This was confirmed by a test of instrument performance (Fig. 4) subsequent to the lung study.

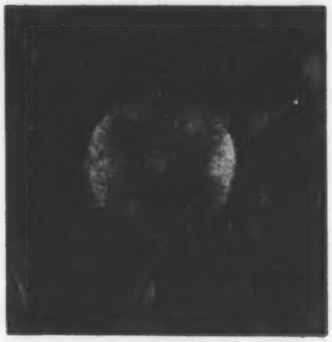

Figure 4. Test of camera response using a uniform plane source of radioactivity.

If suspicions exist and there are quality control test data, the physician can immediately verify whether instrument artifact produced the uptake defectiveness. By itself the lung study is representative of a potential case of misdiagnosis. Perhaps in any event, or at best, the physician is going to call for a repeat study. So we have wasted time by the physician, the technologist, and the patient; a wasted administration of radioactive materials, and a waste of radiation exposure. Had a quality control test been performed before starting the patient examination, all of this waste could have been avoided. This would be medical care service at the least cost with minimal exposure. This is the approach and the kind of examples that we use as incentives in the workshop to encourage implementation of quality control practices.

To the extent available, local talent and resources are used in the presentation of the workshop programs, and this differs from the traditional BRH training program that you may be familiar with, where both instructors and necessary equipment were brought to a particular site to hold a training program. These workshops are set up on an independent basis in consultation with a coordinator for the local nuclear medicine profession.

The workshop follows a pattern of classroom presentations, usually beginning on Friday afternoon. The major topics presented are: signal processing, which is a discussion of the major steps in electronically developing a visual display of radioactive materials in the organ; procedures for quality control testing, including a discussion of the test apparatus that is necessary, the parameters to be tested, the evaluation of test results; and basic troubleshooting--how to identify instrument problems.

The following Saturday morning is primarily devoted to demonstrating quality control and providing the opportunity for each participant to do the procedure on his own. Each participant is given a manual, covering the topics presented, and a quality control protocol appropriate for his instrument. In the nearly 2 years of presenting the scintillation camera workshops, over 600 have attended. This training has provided a useful opportunity of standardizing the practice of quality control for scintillation cameras.

We are also pressing on with other workshops. One deals with safe handling practices of radionuclides and quality control of radiopharmaceutical preparations. Some of the major topics presented in this workshop are: radionuclide generator design and proper usage, radionuclide calibrator quality control, quality control in the preparation of kit-radiopharmaceuticals, delivery and containment of xenon-133, radiation safety and radioisotope handling, and rules and regulations for byproduct materials and recordkeeping.

Also in this workshop, a hands-on laboratory experience is provided. Among these are: decontamination of a "hot" lab--(I find it rather amazing how few people know how to go about decontamination for a spill on the floor; many take up decontamination as though they were preparing a patient for an injection and they start swabbing in the middle and work outward); quality control testing of generator eluants; particle size determination; determination of percent binding of radiopharmaceuticals; and quality control procedures and materials used for a radionuclide calibrator.

Hopefully, this next fiscal year, we will be able to present this workshop in at least six locations in various parts of the country. At the same time, we will be devising a workshop for another imaging instrument--the rectilinear scanner. Following these will be the development of quality control workshops for the in vitro aspects of nuclear medicine.

If any of these programs are within the scope of State radiological health programs, or you would like to use them as an opportunity to extend your outreach or your service to the medical community, please let us know. We would be delighted to work with you. Let Dr. Paras or myself know of your interest.

IMPLEMENTING QUALITY ASSURANCE IN NUCLEAR MEDICINE

Peter Paras, Ph.D.
Director, Division of Radioactive Materials and Nuclear Medicine
Bureau of Radiological Health, FDA

One way of implementing quality assurance was very well described by Mr. Van Tuinen--the teaching approach. We have followed this approach in the past, and we will continue to do so until this program is widely available through the Technologist Section of the Society of Nuclear Medicine. They will try to implement this teaching program through their continuing education program.

Another way of implementing quality assurance is through the standardization process. In this respect, we have done some work in trying to promote a simple, workable quideline which can be used by the various departments of nuclear medicine around the country. We have been working together on this project with the Society of Nuclear Medicine, the American National Standards Institute, and College of American Pathologists, who have been working with the National Bureau of Standards, and getting advice from the American Association of Physicists in Medicine, the American College of Radiology, and other interested professional organizations.

We recently came to the conclusion that a guideline of this type is viable, and very necessary. Mr. Van Tuinen showed you an example that could improve and assure the best quality of information and minimum dose in this area of nuclear medicine. There are no guidelines at the Federal or State level with the exception of that published by the Joint Commission for Creditation of Hospitals, which I will read for you:

> "Standard III. There shall be quality control policies and procedures governing nuclear medicine activities that ensure diagnostic and therapeutic reliability and safety of patients and personnel."

In the interpretation of this, they include, "Quality control procedures shall be developed to guide personnel in the standardized performance of diagnostic studies and therapeutic procedures, and to ensure that the identity, strength, and integrity of all radiopharmaceutical agents are maintained.

Having this in mind, I think I will not go into details. Mr. Van Tuinen explained to you why this is needed, and the scope of his work. I will go directly to the recommendations we are proposing, which are as follows:

A. Quality control tests should be performed daily. They should be simple and designed to be completed in less than 15 minutes.

B. A daily quality control program for scintillation cameras consists of the following components:

   (1) Photopeak position and window width settings appropriate to the radionuclide being used for the test;

   (2) Field-flood image as a qualitative check of uniformity; and

   (3) Bar phantom image as a check on spatial distortion and resolving power.

C. The field flood and bar phamton image should be carefully scrutinized and compared with those obtained previously under similar conditions. The best images for comparison are those obtained at the time the device was set at optimum performance. Any slight change that is noticed may be an indication of the slow deterioration or maladjustment of a camera component.

D. All test images should be properly labeled and retained for immdediate reference, preferably in the form of a log book. On a day-by-day basis, a change may not be noticeable, but by comparing test images over longer time spans, subtle deterioration may be detected.

E. A review of these images should be made on a weekly basis to detect long-term deterioration, which may not be apparent on the basis of daily inspection.

We plan to publish these recommendations as a Bureau of Radiological Health publication, and we will invite your comments. We probably can have your input incorporated in our document if we see your comments no later than the end of May.

This will be the first of a series of guidelines we plan to promote in this area. The next will be on the handling of radioactive materials and dose calibrator handling. We will then follow with scanners and in vitro work.

We will welcome your comments, and we hope that this document will be of use in implementing your programs.

INTERFACING JCHA NUCLEAR MEDICINE STANDARDS WITH NUCLEAR MEDICINE LICENSING REQUIREMENTS

Goldie L. Watkins
New York State Department of Health

Who needs quality assurance? The patient, the technologist, the physician, the public, and you in terms of your efforts to maintain radiation exposure to each of these groups of persons to "as low as is reasonably achievable." If everyone needs quality assurance at each rung of the nuclear medicine ladder, who is responsible for seeing that appropriate quality assurance procedures are implemented? Of the several variable inputs to the nuclear diagnostic system, I'd like to focus on "Nuclear Detection Devices" (Fig. 1).

The Joint Commission on Hospital Accreditation (JCHA) is responsible for the identification of quality of service in hospitals through a program that attempts to define the standards or optimal setting in which the service is provided. Furthermore, it periodically attempts to measure existing conditions in the hospital against these standards. It certifies hospitals based on evidence that the hospital's governing body, personnel, and medical staff have collaborated to seek excellence and have demonstrated substantial conformance with professionally developed and nationally applied criteria.

The U.S. Nuclear Regulatory Commission and the Agreement States are responsible for protecting public health and minimizing danger to life or property from radiation hazards. The regulatory programs are designed to achieve this goal through a system of licensing. The licensing program includes considerations of patient safety and drug efficacy as well as radiation safety of physicians, technicians and members of the public. In general, the requirements for approval of an application for a medical license are that:

1. The proposed radiopharmaceutical is one which is safe for the patient and effective for diagnosis, therapy, or obtaining desired investigational information;

2. The proposed equipment, facilities, and procedures are appropriate for the effective use of the radiopharmaceuticals and are adequate to protect the health and safety of the patient and the public; and

3. The drugs will be used by physicians whose training and experience in the basic characteristics of radioactive materials and the clinical use of radionuclides are sufficient to assure safe and effective use of the drugs.

You will note that none of the above items relate to the day-to-day performance of instrumentation used in collecting diagnostic data. Yet the performance of such instrumentation, or any instrumentation for that matter, is known to vary and such variances can be tolerated only within a specified range. Because the information content of gamma or scintillation cameras, in particular, is at best marginal in contrast to diagnostic x-ray images, any loss of camera performance results in loss of information which may be critical to correct diagnosis. Hence, there is a professional responsibility to monitor the performance status of scintillation cameras as well as other instrumentation used in collecting diagnostic data.

The Joint Commission on Hospital Accreditation has recognized the importance of conducting quality control procedures by requiring that instrument performance tests be conducted regularly and be recorded for accreditation. In fact, Standard III, under the JCHA standards for Nuclear Medicine Services requires that "there shall be quality control procedures governing nuclear medicine services that insure diagnostic reliability and patient safety." The JCHA interpretation of this standard includes the requirement that "instrumentation calibration procedures, sufficient to affirm proper performance, shall be conducted each day the instrument is used and the results recorded."

After inspecting several nuclear medicine programs, which reported having recently been evaluated and approved by the JCHA, in which deficient quality assurance programs were discovered, JCHA was asked "by what yardstick does it measure a nuclear medicine program's compliance with its interpretation of Standard III?" We were told that "the Joint Commission, in its standards, does not recommend specific procedures for use in evaluating the proper functioning of nuclear medicine scanning equipment, scintillation camera equipment, and dose calibrators. Since specific procedures would be constantly changing with time, it is not practicable to include them in the Standards of the Joint Commission." A copy of the Nuclear Medicine Services Surveyor's Report Form dated June 1975 was enclosed with this response.

The Surveyor's Report Form includes two items which relate directly to our concerns this morning.

1. Survey Item 8 which reads: "Is routine calibration performed with standards having equivalent energy radiations of the radionuclides which are used in patient studies?"

2. Survey Item 9 which reads: "Are instrument calibrations conducted each day the instrument is used?"

March 26, we asked the Joint Commission "what specific instrumentation calibration procedures does the JCHA certification evaluator look for in responding to Items 8 and 9 of the survey form? Under Item 8, does routine mean daily as specified under the interpretation of Standard III?" We went on to note that any guidance the JCHA could provide in terms of the appropriate quality assurance procedures to be implemented in order to assure the proper functioning of nuclear medicine scanning equipment, scintillation camera equipment and dose calibrators would be greatly appreciated. To date, no response has been received.

To show some of the confusion in the area (Fig. 2), note the differences in recommendations of the Manual of Nuclear Medicine Procedures, published by the Chemical Rubber Company, a copy of which is in virtually every nuclear medicine department; and those of BRH, FDA, whose exposure to the nuclear medicine community has been extremely limited. As you view these two sets of recommendations, keep in mind the JCHA interpretation to Standard III which requires daily calibration of such instrumentation.

At this time, I'd like to request your support in our efforts by asking each of you to write the JCHA and request the same information. One request may get lost between the cracks; but not 50.

By obtaining specific guidance from the Joint Commission on nuclear medicine instrumentation quality assurance procedures, we gain the enforcement of such procedures without requiring that they be spelled out in the radioactive materials license application. Furthermore, evaluation of the procedures by the Joint Commission would be achieved on a more frequent basis than our inspection schedules usually permit.

BUREAU OF RADIOLOGICAL HEATH'S COMPLIANCE PROGRAMS - AN UPDATE

Robert G. Britain
Director, Division of Compliance
Bureau of Radiological Health, FDA

On the left-hand column of figure 1, we have tried to outline the four areas of our compliance activities in diagnostic x-ray; factory inspections, quality control, laboratory evaluation, and field tests. Before I go further, I should say that I am going to limit this presentation to just disgnostic x-ray programs for the last year and a half, and what we are intending to do in the laser area. I think that is enough, and probably that is what the present interests are.

On the right-hand side of figure 1, I have listed some numbers to give you an idea about the size of the program; 108 manufacturers. Sometimes the word factory inspection is not quite appropriate. We do some inspections in the factories, but a lot of it is factory consultation. Our biggest benefit there is interchange between our engineers and the manufacturer's engineers and actually seeing the assembly line.

Figure 1. Diagnostic X-Ray Compliance Program

Factory Inspections	108	Manufacturers
Q. C. Evaluation	2600	Component Models
Laboratory Evaluation	14	Systems Tested
Field Tests - By States:	2076	
By FDA	1085	

The quality control evaluation is essentially the testing program reports that are sent to the Bureau and evaluated there. As far as size of program, we are talking about approximately 2,600 certifiable components that we need to look at.

Our own laboratory evaluation is going on at the Winchester Engineering Laboratory (WEAC). So far, they have done about 14 complete dental systems. We were not into the medical area there, because, of course, it is just too complicated to bring that size equipment in.

Field tests; State contracts, so far, have performed a little over 2,000, and our FDA field troops have done a little over 1,000.

Figure 2. Total Certified Diagnostic X-Ray Installations Reported as of April 1976

G. P. Radiographic	3742	Mammographic	308
G. P. Fluoroscopic	504	Chest	387
Combination R/F	2246	Head-Neck	376
Tomographic	485	Panoramic	1828
Angiographic	543	Intra-Oral	8475
Podiatric	99	Cephalometric	242
Urologic	198	Other Dental	132
		TOTALS	19565

Figure 2 gives you an idea of the type and quantity of equipment that has been introduced since the standard went into effect. A lot of these are completely certified systems; some of it is partially certified; there are about 20,000 total systems.

Figure 3 is an attempt to show you the number of compliance actions that the FDA has taken that have not been individual, one of a kind, field problems. These are essentially factory problems that need to be fixed on a nationwide basis. On the left-hand side, I thought it would be interesting to show you where these problems were found. The quality control evaluation means that we either found it by looking at the testing program reports submitted by the manufacturer, or the manufacturer actually informed us of the problem, and, of course, EDRO was responsible for finding at least six items that were of a nationwide matter.

Figure 3. Nationwide Compliance Actions
Medical X-Ray Units

Source	Actions	Units Involved
Laboratory	N/A	N/A
Q. C. Evaluation	7	504
Manufacturer	5	1,160
Field	6	651
	18	2,315

There are a variety of problems. Some of them were kVp accuracy problems, the absence of interlocks on the fluoroscopic system, collimation problems on one of the units, and special purpose equipment.

Figure 4 shows compliance actions for dental units. Figure 3, under laboratory, we had "not applicable," because we were not testing in the laboratory; however, the findings at our Winchester Laboratory resulted in four nationwide corrective actions. The field produced three and initial reports produced two nationwide corrective actions. That is a lot of units to be corrected when you remember figure 2 showed about 10,000 or 11,000 certified dental units installed; 8,000 seems like a healthy portion of them needed some attention in one way or another.

Figure 4. Nationwide Compliance Actions
Dental X-Ray Units

Source	Actions	Units Involved
Laboratory	4	2,551
Q. C. Evaluation	2	1,091
Manufacturer	1	320
Field	3	5,111
	10	8,073

Figure 5 shows field findings of noncompliance. A lot of these are individual, one of a kind, assembler problems, where the assembler did not follow the instructions, and the assembly was not properly done. The dental area looks the best. Most of those were half-value layer problems, and most of them were associated with one manufacturer, so if you eliminate that, at least the field findings showed the dental machines in pretty good shape. In the mobile area, this was mainly source-to-skin distance problems with a couple of manufacturers, and coefficient of variation problems.

I should explain figure 5, before I go on; the total tested were total systems, and some of these included totally certified systems and combination of certified and uncertified components put together in an assembly. When we ran these statistics, we just decided to look at the totally certified systems; therefore, that last column are the noncompliance results of just looking at the certified systems, and these have one or more compliance problems associated with them.

Figure 5. Field Findings of Noncompliance

System	Total Tested	All Certified Tested	All Certified with † 1 N. C.
Dental	1,601	1,309	104
Mobile	374	298	46
Stationary	951	356	145
Fluoroscopic	228	106	55

The stationary systems do not look too good and most of the problems are in collimation. Most of the problems are, in fact, that the assemblers are either not following the instructions properly (maybe the instructions are inadequate in some places) or maybe he is just not following the instructions, period. So, most of these are collimation problems, and I do not know that this particular situation is going to change for another year or so until the assemblers finally learn that they have got to follow the instructions to have these units comply.

Fluoroscopic units; here again, it is mainly a collimator adjustment problem and table top exposure rate problem. These are assembly instruction problems, I think.

I am going to leave the diagnostic x-ray standard results, and go right into what we are planning to do with the laser standard. Mr. Villforth already told you that the laser standard is going into effect this summer. The laser standard is unlike other of our standards; it is unlike the diagnostic x-ray, the television, and the microwave oven, because these are standards for specific products - standards for A TV set; for A microwave oven; A type of x-ray system. The laser standard covers ALL lasers. There are literally hundreds of different applications of products using lasers.

The laser we define here is a self-contained laser that can be purchased off the shelf, plugged in, producing laser light. An example of products containing lasers would be the grocery checkout stand where a laser is incorporated into a larger system.

Figure 6 is a picture of what 1976 might look like. We know about 150 manufacturers. In size, these manufacturers range from huge corporations like RCA, to essentially basement operations. As an example, RCA produces about 140 different models of laser systems; some companies just produce one. We know that there are about 2,000 different kinds of laser models or systems that can be purchased. These manufacturers are located in about 25 States and 10 foreign countries. Forty of these companies are in California alone. In goods and services, I caution you on the dollar figure; these are worldwide dollar figures; however, between two-thirds and three-quarters of these dollar figures reside in the United States. Again, these are self-contained lasers. Accessory and ancillary equipment costs quite a bit more than the laser product alone.

Figure 6. 1976 Market

- 150 Manufacturers

- Goods and Services:

	Million
Lasers	$ 86
Accessories and Ancillary Equipment	201
R & D	83
TOTAL	$ 370

It is interesting to note that about $32 million will be expended by ERDA, the Energy Research Development Administration. ERDA is going to spend this money in laser-related efforts and fusion research and in laser enrichment of isotopes.

We are going to have some similar problems, I think, with laser installations, in that some of these are going to have assembly problems. We are going to have problems similar to what we are having in the diagnostic x-ray area.

As a reminder of some of the other requirements in the laser standard, lasers are required to be classified into four different classes. These classes are based on the degree of hazard of the accessible radiation; the higher the degree of hazard the higher the class number they have to have. There are four different classes; I through IV. Containment is another area; the laser light that is not necessary for the function of the system must be contained. Interlocks and key controls are obvious. Warning labels; the thing to point out here is that there is no warning for Class I lasers. This is extremely important, psychologically, with the grocery store checkout stands. I think with manufacturers, it is obvious that they don't want warning labels on their products; so most of the manufacturers are trying to manufacture these systems so that they do fall into Class I, which we consider a fairly safe level.

User safety information; this information is to be included with the lasers, and also in the advertising literature. The manufacturer must include safety information in the advertisements and in the sales literature, so that the consumer knows the safety requirements of the laser that he is buying.

Special requirements; medical laser systems require additional safety requirements. Surveying, labeling, demonstration, and alignment lasers must fall into a certain class of laser. So there are special requirements for some laser systems.

Figure 7. FDA Compliance Programs

- EDRO
    - Laser RCO's
    - Field Test Equipment
    - Responsibilities
- BRH
    - Q. C. Reports
    - Factory Inspections
    - Compliance Actions
    - Advisory Opinions
    - Consultation

Figure 7 shows what we are going to do, or are doing, or have done. We are presently training four fellows from the FDA field, the EDRO system, and they are going to be taking a 9-week intensive training course at the Bureau and be trained in laser physics, in understanding the standard, how to use the test gear, and how to protect themselves. These fellows are going to be strategically located; two of them are going to be on the West Coast, one in Cincinnati, and one in Boston.

The field test equipment that you saw at the table clinic will cost Approximately $35,000 for one kit. These laser radiation control officers are going to have one kit each, and test procedures have been developed for the test equipment. These fellows will test laser systems and lasers in factories and will test them in use. We will have to test them in use, because a lot of them will be assembled and not available at the factory. We will be performing joint EDRO/BRH factory and quality control visits. They will be training other Federal officers and State people that are interested, and they will be investigating noncompliances, defects, and accidents. BRH, on the other hand, will be performing our routine evaluation of the quality control reports received by manufacturers, and we will be visiting factories with the field people. Of course, we will be initiating complilance action that result from field investigations. The Bureau, as usual, will be issuing advisory opinions, and providing consultation, which is a very large part of our work. We have worked long and hard with the National Bureau of Standards, who have developed a measurement assurance program, and the manufacturers have been invited to participate in this measurement assurance program. There is a fee, I understand. However, there is one free program offered by NBS. For the helium-neon laser, NBS is willing to provide a manufacturer a cross check and instrumentation that he can use for a week at his installation to check his test gear. This is a free service that NBS will offer.

We have pressed for a meeting with laser manufacturers to iron out any future problems. We have met with 15 of them already at the Bureau; 20 more are scheduled. I hope that they will continue to come in.

As a means to encourage laser manufacturers to come on board, we have provided them with a number of publications. One of these publications is on quality control practices for compliance that manufacturers may use as an aid in setting up a quality control program. Another publication is a national conference, held in June 1974, on measurements for laser testing for regulatory purposes. This report is available and has been sent to manufacturers. Other examples of our publications include the test procedures that accompany the equipment for testing, a tabulation of accessible emission limits--to be used to classify manufacturers' lasers in accordance with the standard, a guide for the submission of the quality control and testing reports, and a brochure for laser manufacturers to help them determine whether they are, in fact, manufacturers. We think that we have done a reasonable job, and maybe we have gone overboard; but we learn a little bit with each standard we promulgate. The more of this you can do before a standard goes into effect, the less compliance problems you will have.

INFORMATION SPECIALISTS' ROLE IN STATE RADIATION CONTROL PROGRAMS

Richard Ridgway
Illinois Department of Public Health

175 threats of violence against American nuclear facilities since 1969...

The Brown's Ferry Nuclear Plant Fire...

The Dresden II Malfunction...

Miami's Turkey Point reactor suffers further leakage of radioactive water...

Radium needles lost in shipment somewhere between Omaha and New York City...

Radiation is news, no matter what form it takes. It is perhaps the most controlled, least understood, and most feared form of energy in the world. That is why the Illnois Department of Public Health has elected to follow a policy of complete candor and openness concerning its radiation activities. By pursuing this policy it is hoped that some measure of public understanding and public acceptance for our efforts can be attained. We must learn the lessons that the past has taught us. We need public understanding and support to continue to work. NRC Commissioner Victor Galinsky was quoted in the April 12th issue of Newsweek as saying: "In the end, the real issue in the dispute over nuclear power is safety. We must resolve this question in a reasonable way, so we can truly persuade the public that we are doing all that can be done to insure that the reactors are harmless." Still quoting from Newsweek, "safety was not always the paramount concern that it has now become. Paradoxically, the government and the nuclear industry helped make it an issue by ignoring or hushing up a number of the problems they encountered in the early years of the nuclear business..." Quoting Mr. Galinsky again, "We are still paying for what the AEC did not do in the 1960's."

Today, public information activities are an integral part of the Illinois Department of Public Health's Radiological Assistance Plan. The Illinois Plan provides that prompt and candid public information shall be made by public information specialists at radiation accidents and incidents as required.

Criteria for determining public information actions on incidents involving radiation shall include, but not be limited to:

1. Radiation hazards to the public.
2. Radiation exposure to personnel above guidelines.
3. Contamination, of more than a minor nature, to personnel or property.
4. Circumstances likely to create rumors or exaggerated reports in the absence of official comment or information.

The public information specialist on the Illinois Radiological Assistance Team serves as a liaison between the team leader and the news media. The public information person acts as a buffer to free the team leader and the other team members from the chore of answering basic questions when there's important work to be done without delay and without interruption. The information specialist also serves the news media by providing accurate and current facts about the type of incident that has occurred, when and where, who was involved, the scope of the hazard, steps being taken to prevent or minimize hazards or dangers.

The public information specialist is also trained in photography and provides a photographic record of the incident or accident to be used as documentation and to assist in future training of the team members.

In addition the public information specialist provides information to local officials when appropriate so that they, too, are aware of the radiation accident or incident.

The public information person arranges and coordinates the release of statements from agency officials who may be present at the radiation incident scene.

A report to the associate director of public health on the public information aspects of a radiation incident is filed along with the report of the other radiation response team members.

When information specialists have been involved in Illinois radiation incidents, downtime related to media interviews and interruptions has been reduced. In addition, media people have been assured of a continuous and systematic flow of accurate information. Everyone gets the same set of facts and theradiation professionals are allowed to do their job. The key to the public information specialist's effectiveness in dealing with media inquiries and serving as a liaison between the team leader and the media is training. The public information person must know what techniques are being used to locate a lost radium souce...must be familiar with the precautions that individuals exposed to the source should follow...and most importantly must be able to explain these things in terms people can identify.

Of equal and perhaps greater importance to training is involvement, getting your public information people in on the takeoffs, not just the crash landings. Primary involvement of the public inform;ation team member will make that person a much more effective team member and save youthe trouble of playing catch-up when the heat is on. Even a very good information person cannot communicate or explain what he does not know.

Radiation is news and the activities of your radiation control programs will undoubtedly be given a great deal of attention. Public information is a vital part of our radiation control effort in Illinois and we think it is going a long way toward furthering public understanding and support for the important job of radiation control that must be done.

SESSION: EMERGENCY RESPONSE EXPERIENCE

Moderator: *Margaret A. Reilly*, Pennsylvania

ALABAMA STATE RESPONSE TO THE BROWN'S FERRY NUCLEAR PLANT FIRE
Aubrey Godwin, Director, Division of Radiological Health, Alabama State Department of Public Health

STATE EXPERIENCE IN IMPLEMENTING PROTECTIVE ACTION GUIDES
John R. Stanton, Director, State Radiation Control Agency, New Hampshire State Department of Health and Welfare

MICHIGAN'S RESPONSE TO "THE DAY WE ALMOST LOST DETROIT"
Donald E. Van Farowe, Chief, Radiation Division, Michigan Department of Public Health

SESSION: MAMMOGRAPHY - ISSUES AND OPTIONS

Moderator: *Reynold Brown, M.D.*, California

THE ISSUES: THE NEED FOR MAMMOGRAPHY SCREENING
Myron Moskowitz, M.D., Project Director, Breast Cancer Detection Center, University of Cincinnati Medical Center

THE ISSUES: BENEFIT - RISK IN MAMMOGRAPHY
Richard P. Chiacchierini and Frank E. Lundin, Division of Biological Effects, Bureau of Radiological Health, Food and Drug Administration

THE OPTIONS: EQUIPMENT AND IMAGING CONSIDERATIONS FOR MAMMOGRAPHIC PROCEDURES
Robert Jacobs, Assistant Director, Division of Electronic Products, Bureau of Radiological Health, Food and Drug Administration

THE OPTIONS: MAMMOGRAPHY QUALITY ASSURANCE PROGRAM
Ronald G. Jans, Division of Training and Medical Applications, Bureau of Radiological Health, Food and Drug Administration

THE OPTIONS: NYC MAMMOGRAPHY REGULATIONS
Leonard Solon, Ph.D., Director, Bureau of Radiation Control, New York City Department of Health

ALABAMA STATE RESPONSE TO THE BROWN'S FERRY NUCLEAR PLANT FIRE

Aubrey Godwin
Director, Division of Radiological Health
Alabama State Department of Public Health

To give you a little background on the Brown's Ferry Nuclear Plant, it is the largest currently operating plant in the world. We were ready for fire. On March 22, 1975, approximately 12:15 p.m., a worker in the spreading room was testing the sealing between the cable penetrations between the spreading room and the reactor building. The spreading room was at a slight positive pressure with respect to the reactor side. He was using a candle. All the rumors you have heard about a candle are confirmed; yes, he was using a candle to check these penetrations.

The polyurethane spray that he was using caught fire. He proceeded to try to beat it out with a flashlight, and he used a CO_2 extinguisher. Unfortunately, since that room was positive pressure with respect to the reactor room, it was like a cigarette, and the fire was being pulled into the reactor side of the penetration. So the CO_2 was not effective.

At about 12:35 p.m., they turned in the fire alarm, officially. There is a little confusion about how the fire alarm was turned in. At 12:51 p.m., approximately, the operator on Unit One "scrammed" off the line. It was a manual scram, and it was successful; no problems with it. At approximately 1:00 p.m., Unit Two was "scrammed" likewise. Although part of the scram signal had already been received by the Unit Two operator, he completed it. Both operators confirmed that all control rods were in.

During the next 7 hours of the fire, many systems were lost which related to the basic emergency core cooling system and reactor safety controls. Essentially, the entire emergency core cooling system was lost and the ability to operate the relief valving manually on Unit One was lost; however, the automatic functions for the relief valves were operable. At 3:20 p.m., I received a call. March 22 of 1975 was a rather beautiful day in Alabama; great for cutting grass, which was what I had just completed, taken a bath and walked out in all glory and the phone rang. Then I made my mistake; I answered it.

For the next 7 hours, I did not get off of the phone, except to get dressed and to run out and get my handy list of emergency phone numbers to call. On receiving the initial call, I concluded that, yes, they have a problem. From their radiation monitoring data that they were giving me, it did not appear that we had a radiation emergency, but they certainly had a major problem at the plant, and that appropriate notification should be made to selected officials in the counties and State to be aware of the situation. We had a situation with a potential for deteriorating and we should activate to that degree the emergency plans for the State of Alabama.

I started the activation for the plan. I tried to notify the appropriate Government officials, including the State health officer, who was out of town, from whom I have delegations; that left it with me to decide how to go.

By 4:20 p.m., I began to learn all the gruesome details of how much was inoperative, and reevaluated the situation, still concluding that we did not have a radiation emergency, but we certainly had the problem with the coolant to the reactor itself. By this time, I had been informed by the State coordinating agency which officials had been notified in the local government and he recommended, and I concurred, that since we were not requesting any action by the officials that we would discontinue notification, unless the situation appeared to deteriorate to the point that we were actively going to need these officials. So we did terminate notification at that point, then we proceeded to follow the course of the action throughout that evening and the next day and actually until now for a little over a year.

The problems we ran into; approximately 6:00 p.m., whenever they lost the ability to operate the relief valves, they lost the ability to use the condensation system to add to the water to the reactor vessel. As the pressure rose, they were using the control rod drive pumps to add approximately 130 gallons per minute of water to the reactor vessel. They needed 218 gallons per minute to maintain cooling indefinitely. (These were details, I might add, I did not know that night; I did know that they needed some, but I did not know the exact quantities. I did know that if isolation occurred, that is, the inability to add coolant, our reactor would have at least a couple of hours before the core was uncovered and possibly to the panic of everyone, a melting would be an imminent problem.)

As we went through the incident before, the core cooling became the critical situation. They had restored the relief valve manual operation and were able to go back on the condensate booster pump and add some water. During the high pressure phase, after they lost their ability to operate the relief valves, they did have the capability of adding enough water at all times. They even had a couple of backup systems. So the details about how close were we to a meltdown is hard to answer, because they always had a least one backup system (actually, they had two backup systems) available on line. I don't know how you decribe it as being close when you have that kind of backup, but that was the situation.

During the course of the fire, the Athens fire department was called at 1:00 p.m. They were actually in the reactor building at 1:45 p.m., and they had no problems. The firemen were not particularly frightened, because TVA had taken time to go down to talk to the local fire department, explain how to get in there, the types of problems they could expect, and had set up a dosimetry program for them (film badges and dosimeters). When they came in, they were properly monitored. The firemen had some concept of the type of radiation problems they would be involved in and who the people would be at the plant that would be advising them of their radiation problems.

The fire was finally put out at 7:30 p.m. The fire chief had recommended at approximately 2:00 p.m. that water should be used. Water was not used until 6:45 or 7:00, and when it was used the fire was put out. There have been a lot of questions about the decision that was made not to use water until that time. I don't know anything about fighting fires; I can tell you what both sides say. Some say that they should. TVA's position was that they were losing systems that they did not think that they could lose, and they would not want to chance shorting out any additional systems until the reactor safety conditions were stabilized. I don't know the answer about firefighting, but that is part of the things that occurred.

After we activated our plans, we did call the local officials as they were available, and did find a few things in our plan that were embarassing, some of which I don't have a total answer. I will read you some of the conclusions from the I. D. Report.

The plan was out of date. Yes, our telephone numbers were out of date. We did not have a positive system for trying to update the telephone numbers. We depended upon people, when they moved or changed, to notify us. We are trying now to make a positive system. We are, approximately quarterly, contacting those people down the line, saying check your list and let us know if there are any changes. In addition, we are trying to tell people when you move, let us know your new telephone number. It turns out that when John moves, I know John moved; I know his new telephone number; doesn't everyone? So, this is the problem, trying to get these numbers back up and into the official list. We feel that by doing it quarterly, even if it doesn't make it to our list, that at least for 3 months, we understand that Ma Bell will put that number on intercept and divert calls to the new number. So even if we should call the old number, with a little luck, Ma Bell will come through and say the new number is ___, and will go to it. It is a problem in getting these telephone numbers into a directory; people do move; they don't know their phone numbers until after they have moved. It takes the U.S. mails at least a day or two to get mail anywhere in Alabama back to us; so for a few days, at least, we will have this problem at any time.

There was also a comment made regarding our briefing of new local officials. Again, this is a decision on several State agencies' parts that you have a new man going into office, give him a chance to find out what he is supposed to be doing, then brief him. In the interim, depend upon the local disaster officials to give him the essential information he needs, until we can give him a full-fledged briefing. We have changed our thoughts since the fire, I might add. When he gets elected, he will get a briefing, whether he is in office or not. The one official involved, who had not been briefed, does know how to evacuate folks; he may not have known the specific details of the Brown's Ferry thing, but he had some experience on evacuating before this went on, so we feel fairly confident that he could have done the job, although this was not put to the test, and I can't say for sure.

The basic thought in our whole plan is that no one person or agency creates a critical path. So, if something on the normal path is not available, because of lack of briefing, or out of town, or whatever, you have an alternate path or agency (in many cases, these are agencies, not just individuals) who can perform the same function, although it is not their prime function. I think that you should look at your plans in this concept.

Another point that was raised - the air sampling unit was out. This was quite true, although the air sampling units are not used to make a protective action decision, but only to document what materials might have been in the atmosphere. The air sampler was out; it was broken some months before. Our program was not sufficiently funded to provide spare air samplers. We did eventually get another agency's air sampler on line and take some air samples downwind around the reactor to confirm some of the available data from the reactor. Since then, we have purchased additional samplers.

The legislature, in its wisdom, deleted our budget from the specific legislative bill, and put us, radiological health, as well as all other agencies in the Health Department, into one budget for the Health Department. The Health Department budget operating base in Alabama is approximately $8 million. That does not include Medicaid. The legislature gave the Health Department an additional $100,000; also approved a 25 percent increase in travel expense and a 5 percent across the board raise to all employees. The Health Officer was kind enough to give my division an additional $20,000, which is one-fifth of the $100,000 addtional provided by the legislature. As far as funding is concerned, yes, I have additonal funding from the Brown's Ferry fire. It was earmarked for equipment. We are in the process of buying additonal equipment to monitor around the reactor.

The Report also commented on our minimal efforts to contact the local officials. As indicated earlier, it seemed rather ridiculous to call up folks and tell them they had nothing to do, particularly when they were obviously at home, and were not going to be called by their constituents.

The fourth point covered by the Report was communications between TVA and the State focussed on plant operating status rather than offsite radiological releases. The use of this phrase, this does cause me some concern, because it seems to imply, and maybe I am overly sensitive on this, that perhaps we were unwise to continue to look at the plant status during the fire. Our feeling is that we need to know what is happening at the plant to project the potential offsite consequences. I think that many of us would agree with that, and we are working on that assumption through the State. At this time, it is a statement of fact, and other than someone might draw a conclusion that this was an error, I have no problems with it. I still think that it is proper and think that whenever you are in the middle of these emergencies, you need to know what the plant status is.

To look at the fire a little bit, figure 1 shows the area where the fire started in the reactor. The cable trays are on 9-inch centers; they are about 14 inches wide. They go through the wall to the reactor and they have polyurethane dam foam sprayed in between them. The fire was put out fairly quickly in the speading room, but acting as a cigarette, is you would, the fire was pulled rather quickly through to the other side. I say rather quickly; actually it was about 4 hours after the start before it was finally confirmed as being out in the spreading room. We have a lot of smoke; it is a very confined area in the spreading room. A larger part of their problems was the smoke; they could not see. Breathing apparatus became a premium at the plant. They were getting breathing air from Nashville, Chattanooga, NASA; they even dicussed the possibility of us bringing our two cylinders up from Montgomery. There was a definite need for air to fight the fire.

Figure 2 shows the other side of the wall. The spreading room is about 6 feet high; it is very crowded with these cables; the point has been referred to many times is that it is crowded. Where is comes out it is about two stories high. The fire was about 20 feet above the floor. They had to climb up on scaffolding to fight the fire; they could not see; they would climb the scaffolding, fight the fire for a few minutes and have to come back down. The fire melted the light bulbs. The Unit One reactor is to the right of figure 2.

In conclusion, I would like to give you a bit of philosophy in the form of a parable. A kindly peasant was walking through the forest one winter day, when he came across a small bird in the last stages of exhaustion. He put the bird under his coat to restore it, and walked until he came to a very large moose. The moose squated down and deposited a enormous pile of steaming lifegiving nutrient upon the ground. The peasant, finding the small bird had not recovered, thought it might benefit from such natural benefication, placed it on the pile with just its head showing. He then walked off, and out of our story. The bird did, indeed, recover and in its delight, began to sing. Unfortunately, a passing wolf heard him singing, and came over to the pile, saw the bird, and bit off its head. There are three morals in the story. A. Do not always assume that the man who dropped you in it is necessarily your enemy. B. Do not always assume that the man who gets you out of it is necessarily your friend. C. When you are in it do not sing.

Figure 1. Fire starting area.

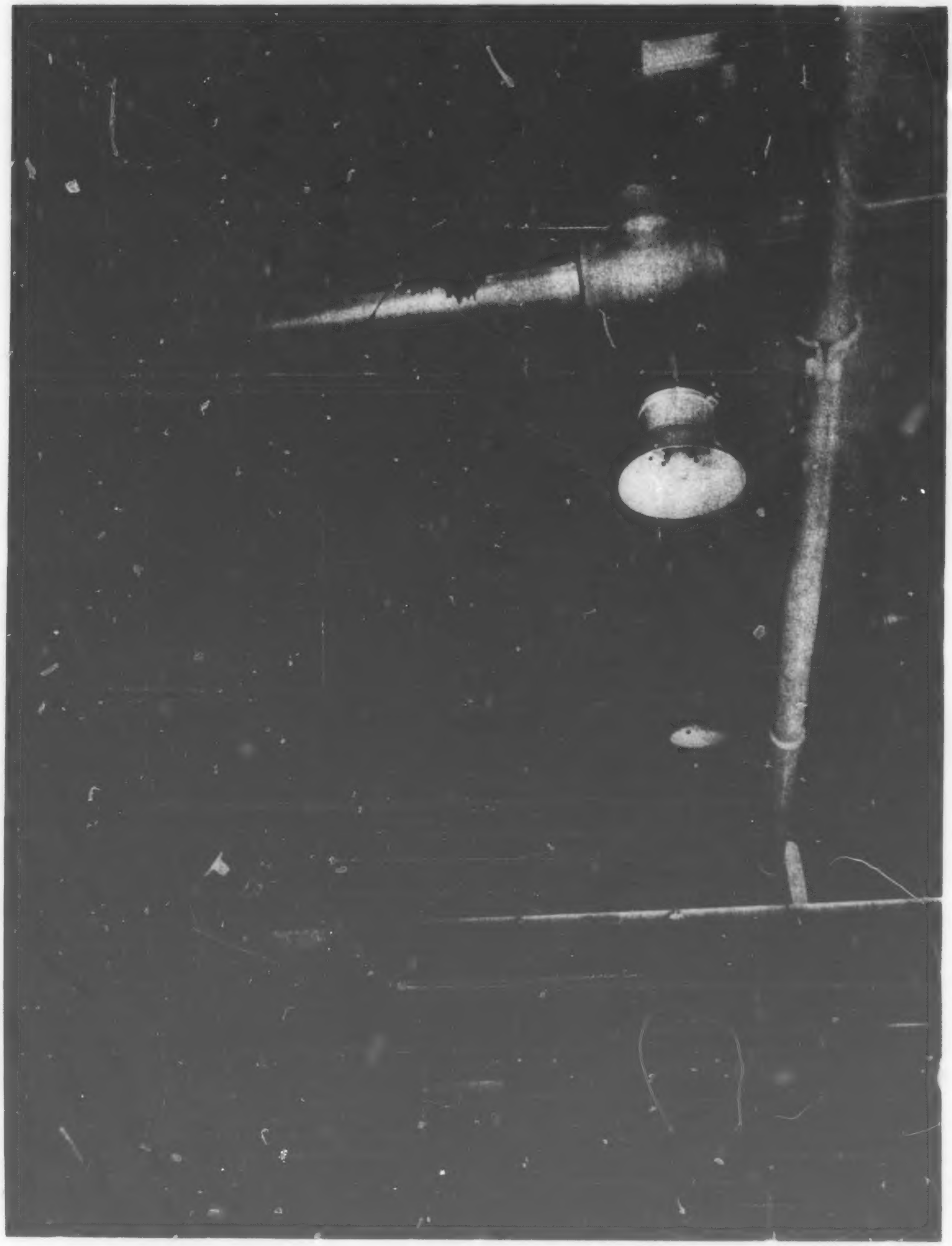

Figure 2. Major damage area.

STATE EXPERIENCE IN IMPLEMENTING PROTECTIVE ACTION GUIDES

John R. Stanton
Director, State Radiation Control Agency
New Hampshire State Department of Health and Welfare

As with so many aspects of radiation protection, we seem to recognize the problem soon enough and expend considerable effort and soul searching in pursuit of a solution, only to then stand idly by - hoping to hear some magic words of guidance from on high. Such has appeared to be the case with Protective Action Guides (PAG's) and Protective Actions (PA's) for nuclear incidents. Understandably, we are reluctant to commit ourselves to setting levels at which we will implement (or order implemented) protective actions. Equally are we reluctant to say what those Protective Actions may be. Reluctant for many reasons, paramount among which is the inevitability of being called upon to publicly defend these levels and actions.

Our Agency, with its legislative mandate to develop criteria for protective actions for fixed nuclear facility emergency response planning, had long dwelled in this valley of reluctance - until sheer frustration dictated that we not just sit there, but do something. Fixed nuclear facilities were near - and soon to be here. Responsible (and irresponsible) individuals and groups were demanding commitments. And commitments they have obtained. I would like to share with you some of our experiences in this regard.

In the early days of abode in this dark valley, it is not that we were lacking in guidance from on high. It is just that the guidance was in draft form. Part of our frustration came from phrases such as "these protective action guides are preliminary and may change. They are shown here to illustrate the types of numbers that can be expected in final guidance." As we are well aware, the final guidance is here - at least a portion of it - and the "types of numbers" have jelled into "the numbers;" or have they? But, more about that later.

The guidance in its draft stages, then, afforded much more assistance than most of us were willing to ascribe to it. After all, these documents were not simply dreamt up by the authors; they had firm foundations in the opinions of many standard-setting bodies. The only task remaining was that of taking the bull by the horns and, using their guidance criteria, adopting levels that were deemed appropriate for our situation.

You will note the constant use of the nominative plural "we." As frustrated as I had become, I still retained some of the vestiges of the reluctance of the early days, and so hesitated to stand alone in defense of whatever levels and actions might be adopted. Many of us have at our disposal committees or commissions which act in an advisory capacity to our respective agencies. Although it is not statutorily designated as a standard-setting body, we felt that our Radiation Advisory Committee had the power to do exactly that - advise, on such levels and actions, and that the Agency could feel more secure concerning their adoption. Such a committee can then act as an additional filter for the guidance from on high and can broaden the base of responsibility for consequences of any levels and actions adopted. Armed with guidance aplenty and new found confidence we began, and are continuing to set protective action guides and to choose protective actions to be implemented. PAG's and PA's can,

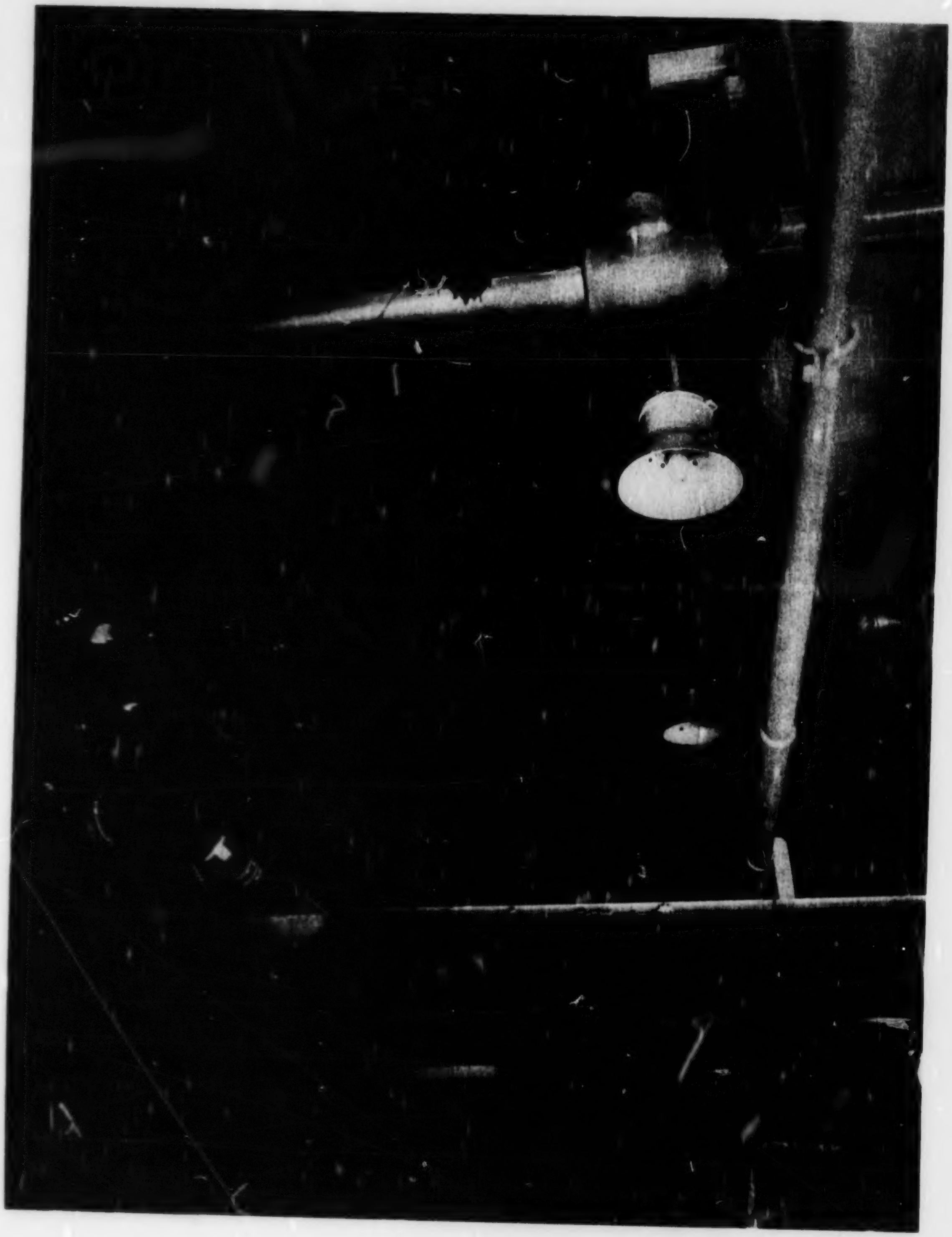

Figure 2. Major damage area.

of course, be set for the short-term and the long-term. Our concern up to now has been the former. Thus far the Agency and the Committee have set PAG's for whole body from noble gases, for thyroid from inhaled radioiodines, iodine-131 concentrations in milk, and iodine-131 concentrations in drinking water.

Whole body and thyroid PAG's involve three ranges: Range I within which the Agency will not ordinarily consider the implementation of protective actions, unless their implementation could be effected with little inconvenience to the potentially affected public; Range II within which the Agency will consider the implementation of protective actions and act in accordance with constraints existing at the time of the incident, such as high transient population density and adverse road and/or weather conditions; and Range III within which the Agency will order protection actions, to include evacuation (the last resort), except in such cases where the action is patently impossible. The PAG's thus set are as follows:

	Range I	Range II	Range III
Whole Body	0 to <2 rem	2 to <25 rem	25 rem and over
Thyroid (child)	0 to <10 rem	10 to <125 rem	125 rem and over

PAG's for iodine-131 concentrations in milk and water involve only two ranges, those of acceptance or rejection. The Agency, with the advice of the Committee had elected not to retain the option of diverting milk to milk products, allowing for decay of radioiodines to acceptable levels. This decision also has the concurrence of State dairy farmers. PAG's for milk and water are as follows:

	Accept	Reject
Milk	0 to <60 nCi/l	60 nCi/l and over
Drinking Water	0 to <10 pCi/l	10 pCi/l and over

You will no doubt recognize these numbers as, at least, products of guidance contained in EPA's PAG manual and draft drinking water standards and guidelines, and FRC Report No. 5. The numbers assigned are, for the moment, hard and fast; however, this does not imply that they cannot be altered. The Committee and the Agency are open to suggestions from interested parties.

Taking the bull by the horns has not, of course, solved all our radiation emergency response planning problems. In fact, it has created others - or at least brought them to light. The first of these is accident assessment. Until such time as better, more timely methods of actual field measurement of gamma dose rates and radioiodine concentrations are available, we have chosen to evaluate plume effect from data supplied by the facility concerning the release. Lacking any pertinent data items, such as quantity and type of release, expected duration, status of engineered safeguards, wind speed and direction, atmospheric stability class, and the like, conservative assumptions can be used to arrive at dose projections.

Another potential problem is that of differences of opinion (or lack of opinion) among responsible agencies in neighboring States. The Region I States, the State of New York, and utilities in the Northeast have met in an attempt to resolve these differences. The initial meeting only confirmed that these differences exist, but we are hopeful that more positive results may be forthcoming from future deliberations.

Finally, one of the Conference members has posed a question concerning dose levels contained in 10 CFR 140.84 versus those contained in EPA's PAG manual. While it is true that the former document outlines criteria for determination of whether there has been an extraordinary nuclear occurrence and is "not intended to indicate... a level at which some type of protective action is indicated," this individual asks, "Should a State adopt PAG's contained in the latter document (or any other PAG's more stringent than levels outlined in 10 CFR 140.84), would that State be required to provide indemnity in those cases for which Part 140 does not provide?" I have no answer for all States; but, for what it is worth, our Attorney General's Office issued a resounding "no" to the question.

As usual, a few answers generating a multitude of new questions. But we are confident that determination in seeking answers, and in manufacturing them if need be, is the way to go.

MICHIGAN'S RESPONSE TO "THE DAY WE ALMOST LOST DETROIT"

Donald E. Van Farowe
Chief, Radiation Division
Michigan Department of Public Health

The book, "The Day we Almost Lost Detroit" was written from the antinuclear perspective, which can be justified because of the economic incentive. A pro-nuclear power book would, afterall, never make the best seller list, but apparently this one hasn't, either.

The author has researched the technical and documentary sources well, which in the public's mind gives credibility to conclusionary phrases and statements interwoven throughout the book. He uses such statements to create dramatic effect and to hold the reader's interest. This literary technique guides the reader to erroneous, calculated conclusions, without reader awareness, and with the artistry of witchcraft, instills fear of the mystic unknown; "the next time," and "what if." The author develops insecurity in the mind of the reader with respect to nuclear power by assuming the hypothesis that any error in nuclear power plant design, construction, or operation will, with all certainty, lead to a public health and safety disaster.

He uses the fuel melting incident at Enrico Fermi No. 1, and concludes that "we almost lost Detroit;" but we didn't, leaving the reader to assume that we were lucky. He makes no attempt to analyze the function and design of redundant safety systems and structures which remain to protect against a public disaster. Other nuclear reactor incidents, such as the Chalk River and Windscale are used to create the mood.

Governmental control agencies are his next target. For this he uses WASH-740 Report as his instrument of attack. I will have to say that the Atomic Energy Commission in the past and the Nuclear Regulatory Commission to date have provided these fellows with some pretty good instruments to use from time to time. But, I would leave the defense of that document to the Atomic Energy Commission.

The final blow is directed toward nuclear power plants under construction. The author tells of meticulous adherence to standards in the Enrico Fermi No. 1 construction and the blatent carelessness in construction practices today. The impression develops, if Fermi No. 1 nearly destroyed Detroit with its meticulous construction, what could happen with today's careless construction practices?

Design and construction, or operation errors, are not simultaneous with public health disaster. The author's hypothesis is proven wrong by the examples he uses. He mentions in the book, yet contradictory to these examples, he leaves the impression that society was lucky this time, developing a prophetic foreboding of the unknown. Great care went into the design and construction of this plant to limit the effects of such documented errors as the author cites. Designers did not overlook the possibility for error, either in construction or operation, or the redundancy in the safety systems to offset these possibilities. In the laboratory of reality, experience has shown the margin of safety to be adequate, since no public radiation injury has resulted from the incidents cited by the author. Where trust should develop, the author, through the artistry of witchcraft, instills fear of the mystic unknown.

The first study conducted by Brookhaven National Laboratory of the AEC, "Theoretical Possibilities and Consequences of Major Accidents in a Large Power Plant," is known as WASH-740. This report considers different accident conditions and related consequences, but does not make an assessment of accident probability or public risk. In May 1964, the Joint Committee on Atomic Energy requested that the AEC reevaluate the 1957 WASH-740 report. The design of nuclear power plants had changed; they were larger; the fuel burnup was higher, and therefore the nuclear fission product inventory was higher, and therefore the maximum consequences were greater. Their reevaluation considered a reactor with ten times the fission product inventory, and the result was the increase in the potential number of fatalities under similar accident conditions. A minimal and inadequate effort was made to determine accident conditions. The AEC, recognizing the limited nature of the probability studies, decided not to write a formal final report. In a letter to the Joint Committee on Atomic Energy, the following quotes are found:

> "A firm basis has been laid for the belief that the likelihood of major accidents is extremely low."

> "Assuming the same kind of hypothetical accident as those in the 1957 study, theoretically calculated damages would not be less, and under some circumstances would be substantially more than the consequences reported in the earlier study."

The AEC messed up. They misjudged the psychology of witholding the final report, the fiscal requirement, and the time it would take to conduct a meaningful probability study. Failing to issue a final report raised understandable questions in the opponents' and the author's minds. Mr. Fuller uses these failures to create distrust in the AEC and in government in general. The Rasmussen Report, power reactor study analysis by probabilistics and methodology, filled the gap; in part created by failures of WASH-740. The WASH-740 update study fails to answer psychological errors of witholding the formal report of the update study.

Professor Rasmussen, of MIT, undertook the safety study with funds and assistance from the AEC. The study is found in WASH-1400, entitled, "Reactor Safety Study - October 1975." It took 3 years and $4 million to complete. The study concluded that the probability of major accidents involving public safety is extremely low.

Examples of the author's beguiling technique that betrays the reader by his own interest and imagination follows. I have just selected a few from the book to give you an indication of the technique the author used.

> "The phone call came in some time in mid-afternoon of Wednesday, October 5, 1966." (Page 1)

No mention is made that notification of the incident was not required by the AEC, and may not have been made, but it adds to the drama on the opening page. The Michigan Department of Public Health did not know of the incident until approximately 2 weeks later.

> "Any fission product inhaled or absorbed by the skin is deadly." (page 58)

A similar statement, "Any water inhaled into the lungs is deadly" omits the quantity, which is important. Some fission products are absorbed by the skin, others are not. The only purpose of such a general, misleading statement would be to arouse fear.

> "LMFBR's are subject to superprompt critical conditions, and as the AEC well knows, this technical terminology translated into layman's language is an atomic bomb." (page 63)

Extremely pessimistic estimates, assuming one-half core collapse into the other half, would only result in an energy release equivalent to several hundred pounds of TNT. Fermi containment was designed to contain that type of energy release.

> "Those precautions were unnecessary, as the boiling point of sodium could never be reached without disaster." (page 183)

This is typical of a series of statements designed to arouse fear in the mind of the reader, again. If disaster means public, or even plant personel, disaster, then the statement is not true. The boiling point of sodium was reached during the fuel melting incident of October 5, 1966, and no plant personnel or public were injured.

> "As the control rods slowly went through, and the instrument readings reflected this silent power, when the huge pumps sent the sodium syrup through the system, vibrations were felt in the floor of the control room that hinted at the operator's awesome power." (page 183)

The author is setting the stage for impending disaster; vibrations from the sodium pumps could not be felt in the control room. It is located in a separate building. Water is syrup?

> "Even though is was constantly disclaimed, a nuclear explosion could occur if a fast breeder reactor, like Fermi No. 1, was brought to superprompt critical." (page 183)

A significant excursion requires a superprompt critical condition. The area of greater decision involves the conditions to bring such a condition about. The maximum estimated explosion energy in Enrico Fermi No. 1, again, is in the order of a few hundred pounds of TNT. The size of a small Hiroshima-type bomb is 20,000 pounds of TNT.

> "At the same time, it (that is, the primary sodium coolant) would convey the heat away from them (that is, the fuel cans) as it rushed over the steam generator building through closed piped to indirectly create steam. The pipes would be hot enough to boil the water that surrounded them in the heat exchanger without their sodium content ever coming directly into fatal contact with the water." (page 186)

Fatal to whom? Leaks in the steam generator, causing the sodium - water reaction had plagued Fermi No. 1 project, but it was not dangerous. Intermediate heat exchangers do not even place the radioactive sodium of the reactor within the same building as the steam generator.

I could go on and on citing examples of this type. I have many more, but I think that you get the general technique used by the author throughout the book to guide the reader into a position where the reader feels a sense of fear, particularly those persons who are not familiar with nuclear power plants.

The author's stated purpose in this book is to complete the communications gap created by government and industry with the public. When a man writes a book like this, I ask, is he really fulfilling the task that he set out to do; is he really communicating adequately or is he distorting factual information, such as he has done in this book?

I think that it may be of interest to some of you to understand just a little bit about what happened in the Enrico Fermi incident. The sodium flows to the reactor vessel in conduits and up through a perforated plate upon which the fuel elements rest. There are orifices in the plate to allow the sodium flow to go up between the fuel elements. In the bottom of the reactor vessel is a conical-shaped geometrical form. The purpose for it is to prevent melted fuels from assuming a critical geometry. Since if it should melt, then it would puddle at the bottom.

I knew Walter Sisler prior to the time he decided to go ahead with the building of this reactor, and I knew some of the staff pretty well. It was their primary goal to design a reactor that was safe, and they would go to any end in spending money and time to add safety devices. Some of these safety devices were not necessary, but because of the questions raised by critics, they decided to put the cone in to the reactor vessel. It served its purpose.

Since the reactor vessel was stainless steel, and the cladding on the fuel elements was zirconium, they decided at the last minute, relatively speaking, to put zirconium plates over the cone. The plates were pie-shaped, and they were fastened into the stainless steel conical structure with studs. It was one of these zirconium segments that broke loose; sodium coming through the reactor vessel moving upward caused vibration and one of the segments broke loose. It was carried up to an orifice and plugged an orifice, stopping the sodium flow at that point. The incident occurred as the result of trying to be ultrasafe and to prevent undue corrosion.

DISCUSSION

MR. DAY (Illinois Commission on Atomic Energy): I have a question for Mr. Godwin. I noticed in the testimony given in front of the Joint Commission on Atomic Energy, after the Brown's Ferry fire, that you alluded to an agreement that the State of Alabama has with the power plant for reimbursement of any monies that were expended by the State of local governments for incidents occurring at the power plant. Did any of the municipalities, counties or State, bill the power plant for any efforts on that fire? Also, what all does this agreement cover, as far as reimbursement?

MR. GODWIN: Well, we were the only agency that expended any money, and I had forgotten about that possibility. I think I will go back and submit a bill. I had not thought about that. All the other agencies just were warned, that was all they were bothered. We did go up and run some special samples and do some special processing and spent quite a bit of time on it. The agreement, basically covers the cost above ordinary expenses that would be incurred by an agency; the police department had to pay overtime, they would pick up the overtime. They would pay for housing people in hotels, where you have people to house in hotels; extra food, and things that might be spent by local governments, say, during an evacuation. Where you are not evacuating, you might have to divert your cattle to stored feed, and they would pick up the tab for the stored feed. They will not pay for land and things like that. Only the associated expenses of government to take care of the public.

MR. DAVIES: The reports you referred to mentioned a sampler that was inoperable. The question is this; what is the type of sampler, was it made inoperable during the incident; would it have provided meaningful data to you so that you could have taken preventive action?

MR. GODWIN: The sample was downwind; the wind was shifting downwind during the initial phases of the incident. It was a Gelman low volume that would have been equipped with iodine-charcoal filters. It would not have provided information for protective action during the initial phases.

DR. PARROTT: In relation to Mr. Van Farowe's paper, I heard a distortion myself in a public meeting the other day where it was said that the reactors in the United States would provide enough plutonium in one year to cover a four-lane freeway from New York to San Francisco 1-foot deep. Would you believe the guys from the reactor companies sitting there in a forum did not respond? It really would, except for the fact that the freeway would have to be one atom wide. Aubrey, I have stolen something from one of our neighbors in South Carolina or North Carolina, or someplace, but when we update our regulations, I have a C.Y.A. file. We sent out a response slip that says you did or did not get this; so the next time the intervenors show up, I am going to say "they got it; you can't come in deny that." The other thing I was going to say about that was, have you considered getting the utility to reimburse you for all your trips to JCAE, or. . .?

MR. GODWIN: JCAE did not reimburse me, neither did the utility. With our ethics commission, I would have a problem with the utility; I might even have a problem with the JCAE, as a matter of fact. They have problems with these meetings, as a matter of fact. We bill the State and then let the State get reimbursed from these various organizations; we do not generally get paid directly, although I think that has now been improved. I think some of our people may get paid. Regarding your slips, yes, that was about the first thing we instituted. It did not take us long to realize that we really couldn't document whether folks had these plans. There was one statement by a local government man who claimed he did not have a copy. We now get a receipt for it. I might point out that there are other groups that talked about this thing, one of which was the special review committee of the NRC. Some interesting things came out of the special review committee report, one of which was that we need to have more frequent and intensive drills. This was in part based on the statement of the local government official, that he thought that it had been about 2 years since we had had a drill. Of course, in the interim between that time, we had had a couple of tornadoes, a few floods, a few minor things like that. But we had had a drill 10 months prior to the event. We had a drill in May 1974 and one in March 1975. Now, certainly, it does raise some questions in my mind that drills were not making enough impact on the local officials for them to remember when they were occurring. That is one of the things that came out. As a result, this year, we did have a drill in conjunction with the National Guard, in which we simulated the evacuation of 7 miles in all directions around the reactor, not just one or two sectors as might be expected during an event. We went to the people, knocked on the door, if the people are there, we give them a piece of paper that tells them what reaction we expect from them as a member of the public.

MR. ROBERTS (NRC): I understood your thought for updating drills. Would it help to actually carry out the evacuation of the population in drill?

MR. GODWIN: I don't know that that particularly offers a whole lot more than you would get out of any sort, frankly. We provided "bodies" to go through the registrations, provided people going to hospitals; as a matter of fact, during this particular exercise (it was a 2-day exercise by the National Guard), simultaneously with the problems we were having at Brown's Ferry, we had about three tornadoes, a riot in one town, a gas pipeline blowing up, three school buses colliding simultaneously; so we had a lot of things going on during the same time this was going on. I am not really sure that that really provides that much. We are considering, perhaps, asking for volunteers in the families going to the registration center so that they would be more familiar. We are not considering actually saying "you guys better leave; everybody's got to leave." There are a lot of problems there; I am not sure what benefit you would get if we worked that kind of thing.

MS DOLEZAL: I would like to comment on the last question, actually. We did a mock emergency drill, and we did consider actual evacuation, but prior to doing the actual evacuation, we made an assessment of what it would mean in terms of, not just money, although that is a factor - somebody has to pay for that - but the other part of it is anticipated traffic accidents, anticipated heart attacks and other types of medical emergencies, and the fact that though you know it is a mock emergency, other things can happen as a result. It was our determination that it probably is not in the best interest of the public to actually evacuate. We also had the door-knocking problem.

MR. PARROTT: The other problem is liability; what happens if they are injured - it is your fault.

MR. DAVIES: A question for John Stanton. I believe you mentioned certain concentration of radioactivity in food. If my calculations are correct, equivalent to 10 to 30 rad thyroid dose of I-131. Would New Hampshire be willing to accept foods shipped into New Hampshire as a result of a contaminating event -outside of New Hampshire - at those levels?

MR. STANTON: PAG's provide guides, regarding some source of the contaminated foodstuffs.

MRS. REILLY: You mentioned diversion to processed milk products; did you say that you are not going to divert, or you are going to divert?

MR. STANTON: I stated that we would not divert, we would destroy.

THE ISSUES: THE NEED FOR MAMMOGRAPHY SCREENING

Myron Moskowitz, M.D.
Associate Professor of Radiology
Project Director, Breast Cancer Detection Center
University of Cincinnati Medical Center

(From the paper, "Benefit Versus Risk in Mammographic Screening: One Approach," by Myron Moskowitz, M.D.; Eugene L. Saenger, M.D.; Peter S. Gartside, Ph.D.; James G. Kereiakes, Ph.D.; Seshagirirao Pemmaraju, M.D.; Peter Russell, M.D.; and Linda Gardella, M.S. The study was supported in part by the National Cancer Institute Contract # 1-CN-35042, and the American Cancer Society DPBC-11. The authors are deeply indebted to Dr. Harry Maxon for his thoughtful comments and advice.)

As a result of the impetus provided by the establishment of the National Cancer Institute - American Cancer Society breast cancer screening centers, there has occurred a new surge of interest in the potential carcinogenic effects of low doses of radiation on breast tissue. Bailar's mathematical model proposes(1) that annual lifetime mammographic screening of women beginning at age 35 would cause more deaths from induced breast cancer than lives would be saved by detection of spontaneous breast carcinoma.

Yearly, lifetime screening of breasts of younger women is not necessarily the correct or only model to follow. It may well be that good case control and periodicity studies can be developed based upon: a better understanding of the natural history of the disease, historical risk factors, biochemical markers, mammographic patterns(2,3) and other epidemiologic data which may develop.

Currently we recognize that we are dealing with a disease which can be expected to present clinically in 7 percent of the female population(4). The disease, particularly in its later stages, is highly lethal. Sixty-five percent of carcinomas currently detected are in an advanced state when found(4). Survival curves for all stages suggest a continual falling rate after initial treatment, without any evidence of plateau formation for at least a 20-year period(4). This pattern would suggest that once the disease is invasive, treatment by our current methods has relatively little effect. These data could be interpreted to suggest that earlier detection of cancer of the breast only affects the lead time, presuming the patient ultimately dies of carcinoma of the breast. While recent work(5) suggests that combined chemotherapy in advanced cases of breast carcinoma may in fact prolong life and be of benefit, the treatment in and of itself is toxic and not free of significant side effects and dangers. The natural history of early malignant and premalignant disease is not truly known. Ongoing, routine autopsy data of the incidence of premalignant disease and clinically unsuspected cancer, particularly in younger women, is very sparse, although those data which are available suggest increasing incidence with age(6), as one would expect. Clinical data strongly suggest that intraductal cancer and in situ lobular cancer are early malignant lesions and that atypical hyperplasia is a definite part of the premalignant spectrum(6-20). The true prevalence of carcinoma of the breast in the general population is not known. The full capability of detecting carcinoma in its earliest stages by aggressive mammography and physical examination is not truly known, despite earlier studies(21-25). The data of the Health Insurance Program of New York indicate that of 300 breast cancers found in the study group of patients, 132 were discovered as a result of screening. One hundred and sixty-seven breast cancers were found outside the screening process, 45 within 1 year of the last screen, 48 at times up to 5 years after the last screen, and 74 in women who refused screening. This difference might be taken to mean(1) that the carcinomas developed at a rapid rate and were undetectable by screening. It may well be, however, that the 30 to 50 percent apparent interval cancer rate demonstrated in the HIP study could be reduced by a more aggressive appraoch, and freer use of biopsy as the definitive diagnostic test.

Furthermore, it is our understanding from the Health Insurance Program data(1,21-26) that those cancers detected solely by mammography has fewer axillary nodes involved by cancer, seem to have a lower case fatality rate than comparable controls. In fact, only one patient of 44 whose cancer was discovered by mammography alone has died(21,22). Also, their data would suggest that relatively fewer cancers were detected solely by mammography in younger women.

This combination of observations has led us to certain operational assumptions which seem reasonable.

If there is a stage of the disease, which, when treated, shows a survival curve which reaches a plateau, the argument concerning lead time would tend to be obviated. Our data, based on 75 intraductal carcinomas found in 5,385 breast cancer patients in the Greater Cincinnati Tumor Registry, suggests that this stage may be the only one in the disease where an obvious effect of treatment is discernible. At 5 and 10 years, patients are still dying of and with carcinoma of the breast after treatment, but then the curve apparently flattens (Fig. 1). This observation would suggest that the disease is in fact lethal in a certain number of cases, but that approximately 80 percent (absolute survival) of this small group of patients so treated appear to be cured. It might be argued that it is not truly known how many of those patients who survived would have developed a lethal cancer. Since a number of those patients died even after treatment, it must be presumed the others would have also died. Since 65 percent of treated patients with Stage I carcinoma of the breast can be expected to live 20 years, and since this survival exceeds the median expected normal survival of women over age 55, such a yield can be accepted as a reasonable goal for cure in older women. If we are to screen women age 35, who have a mean expectant survival of approximately 40 years, it would be more desirable to diagnose and treat cancers which are more highly curable, i.e., in situ and "minimal" cancers, as defined by Gallager(9,10). Since it is generally well known that carcinomas at any stage are more difficult to diagnose in younger women by either clinical examination or mammography, a more aggressive approach to biopsy in these women is necessary to achieve diagnosis at an earlier stage. Therefore, the hypothesis to be tested is that guided surgical biopsy based upon the screening tests of clinical examiniation and/or mammography will result in a higher yield of curable cases which will be in excess of the presumed radiation-induced neoplasia. If, in the 5 years of continued annual screening, it can be demonstrated that truly earlier lesions (as defined above) can continue to be found in younger women, and a better understanding of the natural history of the disease can be reasonably assessed, and risk factors based upon mammographic patterns as well as other historical and physical parameters can be elucidated, then we would be in a better position to propose and undertake periodicity studies based on these data. In addition, if this aggressive approach demonstrates any validity at all, one would be in a better position to describe and define prospective case controlled studies combining screening, and various treatment regimens.

In calculating cost of such a program, it is relatively easy to assign a dollar cost per cancer found, or to each patient screened. Even this, however, may be looked at in a different reflection depending upon the eye of the beholder. As Garfield has pointed out(27), by looking at the same data one could either say, "It costs $2,000 to detect one true, positive cancer of the breast by mammography in 500 women," or alternately, the most logical, and we

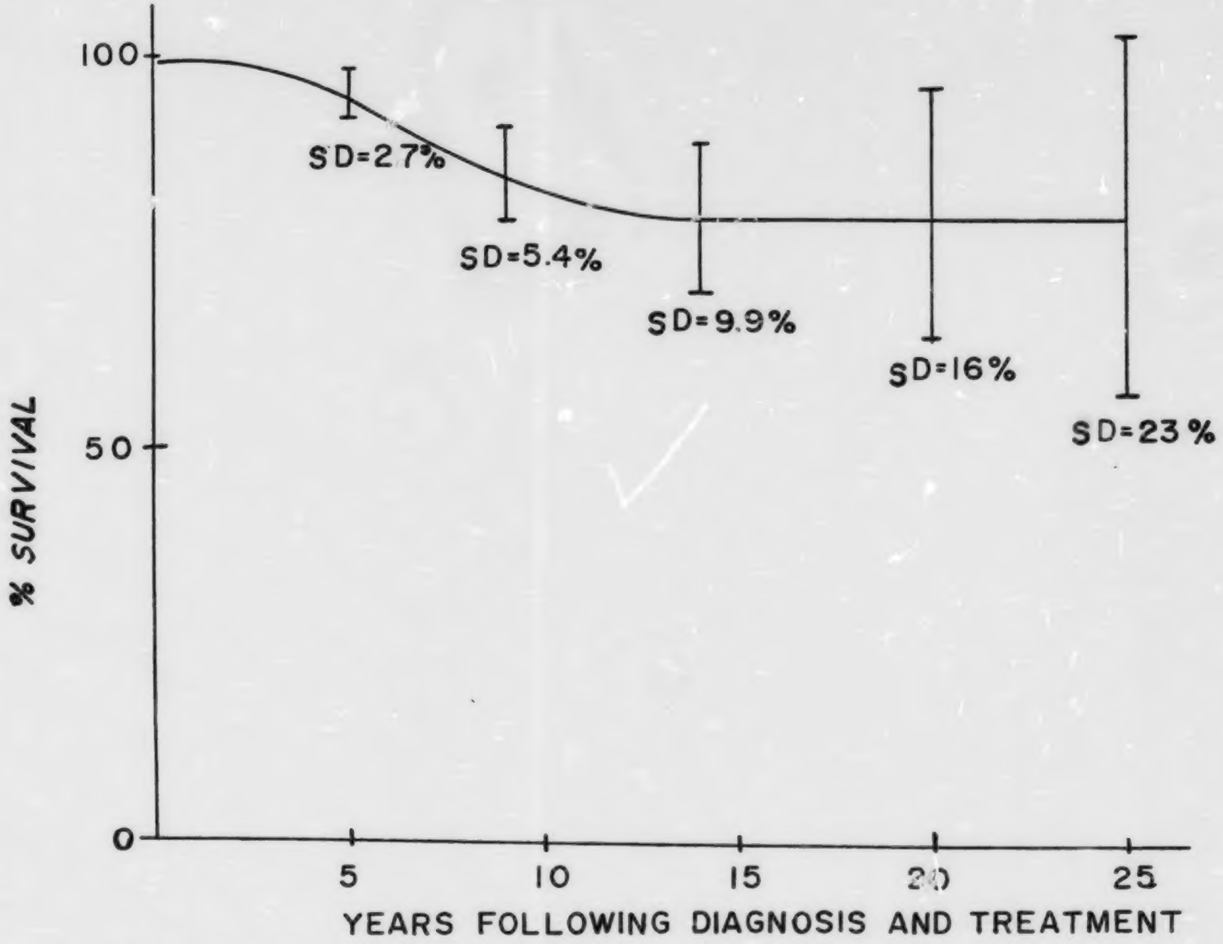

Figure 1. Survival of 75 patients with intraductal carcinoma of the breast diagnosed 1950 - 1969, Cincinnati Tumor Registry. (Survival curve calculated by Life Table Method.)

might add--humanistic statement, "It costs $4.00 each to assure 499 women there is no evidence of breast cancer by mammography, and $4.00 to detect one cancer that through early surgery may have a better prognosis." More tenuous, is assignation of radiation risk of cancers induced by screening. An even more difficult problem is assessing potential benefit.

DEFINITION OF RISK

For the purposes of evaluating risk, several assumptions have to be considered:

(1) The effects of irradiation are linear.

(2) They are nonthreshold.

(3) There is a wide range of absolute risk estimates for cancer induction per 10^6 persons per year per rad given in several reports(28,29). (See Table 5)

(4) Estimation of the degree of cellular recovery occurring after widely separated single doses of low energy, low quantity and high dose rate radiation requires further evaluation.

As can be seen in Table 5, depending upon the presumptions that one makes, there is an extremely wide variation in risk of carcinomas induced. If one assumed total repair, there would be no problem. This is possibly unrealistic(28). On the other hand, assumption of maximum risk under the very worst of circumstances, i.e., no true repair, and maximum absolute risk per rad may well present an overly biased picture(29). For purposes of discussion, we have calculated the most conservative position (upper bounds), a very liberal position (lower bounds), and a moderate position (central bounds) which is not truly midway between the two. This moderate position leans much more closely towards the upper bounds level than to lower bounds. Central bounds assumes linearity and no threshold, as do all positions mentioned above. It also assumes no repair from single dose annual exposure of 1 rad. It assumes that the absolute risk per million patients per year is on the order of 3(29) rather than 6(28). Lower bounds assumes an absolute risk of 0.7 and 80 percent repair(29). Calculations of risk for each of these assumptions are presented in Table 5.

DOSIMETRY

Dosimetric estimations have been based on the data obtained at the Cincinnati Breast Cancer Demonstration Project. The dosimetric data have been derived from lithium fluoride dosimetry and air chamber measurements performed by the Radiological Sciences Division of the Department of Radiology, University of Cincinnati Medical Center. They have been since subsequently documented and verified on a weekly basis by the Radiological Physics Center, Mideast Region, of the Breast Cancer Demonstration Projects, supported by the National Cancer Institute. Our data indicate that an average of 2.8 mammographic exposures per breast per year are made on each screenee attending our center. This includes followup examinations that may be necessary, and repeats for technically unsatisfactory exposures(30). Each patient receiver per year to the breast midpoint an average dose of 1 rad.

DEFINITION OF BENEFIT

In order to assess benefits, we have made certain assumptions: (A) Benefit can be defined, (B) Maximum benefit will accrue to those patients whose cancers are detected when still minimal, (C) The efficacy of mammographic screening at the Cincinnati Breast Demonstration Center can be compared to the efficacy of other current medical surveillance systems extant in our geographic locality by using the rate of detection of minimal carcinomas by the two methods as a yardstick, (D) There is an 80 percent net survival for patients with minimal carcinoma of the breast who receive definitive treatment. This value is thought to be relatively conservative for several reasons. It is not a relative survival figure, but a crude survival figure. It is approximated by previous data reported by Silverberg and Chitale(31) 8 cases of microinvasive cancer. It is significantly lower than the 95 percent 10-year survival for minimal breast cancer reported by Wanebos et al.(32), in 162 patients and is probably representative of what can be expected in the general community rather than in a specialized cancer treatment center.

CANCER DISCOVERY RATES AND PREVALENCE

Our data are based upon examination of two cohorts of women comprising a total population sample of 10,453. A little more than half of this population entered in the second year of screening, and the distribution of patients by age is indicated in Table 1. The first cohort of patients have for the greater part passed through a complete rescreening cycle, and as of December 31, 1975, approximately one-fourth of these patients should be entering into their third year of screening. Cohort B has completed its initial year of screening and is 3 months into its first annual followup screening.

Table 1. Age distribution of patients in BCDC Cincinnati

			Percent of Total Patients
35-44	=	3,792	36.3
45-54	=	3,673	35.1
55-64	=	2,019	19.3
65+	=	890	8.5
< 35	=	17	0.16
Data unrecorded	=	62	0.59
		10,453	

In Table 2, the analysis of cancer detected by stage, age, and modality is given. We have presumed that cancers detected in the second year of screening most likely represented prevalent cancers rather than incident cancers for the most part. We believe this represents a conservative position. Nevertheless, it shall be noted that as of the date of compilation of these data, 15 of the total cancers reported are incident cancers in a little better than 4,300 patients. Three of these 15 are minimal, and 7 are currently Stage 1. (These figures do not include 4 cancers found outside the screening process at 6 to 9 months after their initial screening.)

As can be seen from Table 2, 38 percent of all breast cancers detected by the screening process have represented minimal breast cancer. Perhaps of more importance, is that 10 of the 15 breast cancers detected in the 35 to 44 year age group (67 percent) have been minimal cancer. In the age group 45 to 54, 18 of 46 (39 percent) have been minimal breast cancer. It has been suggested that the relatively high yield of prevalent cancers in this screening group of patients is a result of self-selection. It is true that the screenees are entirely self-selected, which conceivably could introduce bias into the patient population. The possibility would be especially likely if the patient herself were aware of the presence of disease or the concept of staging disease. However, since 53 out of 111 of these patients had impalpable cancer, it would be highly unlikely that the patient herself would have been aware of the condition. It may be that a certain percentage of high risk women bring themselves into the screening process. These women will bring themselves into any screening program that is now or subsequently introduced in an open society.

PREVALENCE

A reasonable "guesstimate" of prevalence of this disease can be deduced. Although previous screening studies have suggested a very low prevalence rate(21-25,33), such estimates may well be less a reflection of true prevalence than a reflection of reluctance to perform biopsy on minimally suspicious physical and/or mammographic findings(2,34-35).

Presuming a previously nonscreened population the prevalence rate of carcinoma of the breast at any point in time should reflect the interplay between the duration of the disease and its annual incidence for years prior to the point in time at which prevalence is determined.

The definition of prevalence is the incidence rate multiplied by the expected duration of the disease(36). In this paper, the incidence rates for breast cancer are available separately by age decade. Hence, the definition of prevalence was modified as follows:

$$P = \Sigma I_j D_j$$

where I_j is the incidence rate of the jth age decade and D_j is the expected duration for a patient with the disease in jth age decade. In figure 2, the computation of the prevalence for the ages 55-65 years is illustrated, where it is assumed that the expected duration of the disease is 16 years.

Simply put, if the duration of the disease is 16 years, and the incidence rate changes every 10 years, then the prevalence at a given point in time is a function of the individual rates occurring within each decade during the time frame of the expected duration of the disease.

In figure 2, Line A varies directly with age and time. Line B is a parallel line denoting 10 years separation. To calculate prevalence at age 65, (the "stop line") the sum of incident cancers for the preceding 16 years duration of the disease) need be calculated. In order to weight the effect of each incident decade the following method is employed. The total sum is represented by the parallelogram encompassed by the "stop line" and its "start line" and lines A and B. That proportion of incident cases occurring in the age group 55-65 is represented by the hatched triangle; that proportion occurring at the incidence rate of age 35-45 is represented by the cross hatched triangle, and the clear area represents the proportion occurring at the incidence rate of ages 45-55.

Thus, of the 16-years duration of the disease, 5/16 are spent in the age group 55-65, 9.2/16 are spent in the age group 45-55, and 1.8/16 are spent in the age group 35-45.

Table 2. Distribution of cancers by decade and mortality

		Mammography Only	Physical Examination Only	Mammography & Physical Examination
35-44	In situ	3	2	1
	Minimal	3	0	1
	Total Minimal	6	2	2
	Invasive	2	0	3
45-54	In situ	8	4	4
	Minimal	2	0	0
	Total Minimal	10	4	4
	Invasive	13 Ca (2 bilateral)	7	8 (1 bilateral)
55-64	In situ	5	0	0
	Minimal	3	1	0
	Total Minimal	8 (1 bilateral)	1	0
	Invasive	7	8	8
65 +	In situ	2	0	0
	Minimal	1	2	0
	Total Minimal	3	2	0
	Invasive	4	2	7

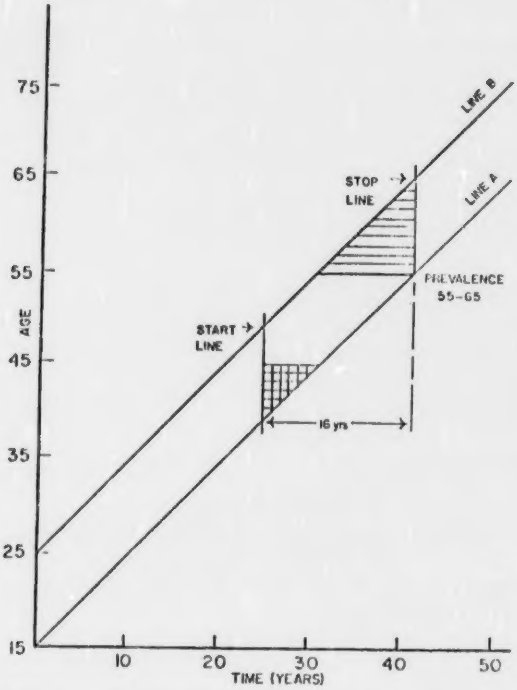

Figure 2. Proportion of years in each decade for breast cancer with median survival of 16 years, to calculate prevalence for ages 55-65.

Therefore, prevalence at age 65 should be as follows:

Age Group	Incidence/1000/Yr.	Expected Duration Time Decade
55-65	1.625	5.0 = 8.125
45-55	1.375	9.2 = 12.65
35-45	0.960	1.8 = 1.73
	Age 65 Total Prevalance =	22.505

Similar calculations have been performed to predict prevalence at ages 45, 55, 65, 75 for disease duration of 10 and 16 years. The results are shown as ranges in Table 3.

The incidence rates assumed for carcinoma of the breast per thousand women are: Age 25-35 = 0.22; 35-45 = 0.96; 45-55 = 1.375; 55-65 = 1.625; and 65-75 = 2.11.

Accurate median survival time of untreated breast cancer is difficult to determine. It presupposes complete knowledge of the natural history of the disease. Survival time of untreated breast cancer, available from earlier literature, is merely representative of time of survival after discover of late or end stage carcinoma. On the other hand, it is conceivable that mean survival rates following therapy could have been altered by that treatment. However, for reasons indicated earlier in this paper, we are assuming that natural history of breast cancer, once invasive, may be little altered by surgical treatment. Furthermore, survival data, to date, have been little affected by discovery of intraductal carcinomas as they have heretofore constituted but a small fraction of cancers detected. Since we believe that in situ carcinoma of the breast is indeed carcinoma and should be represented as part of the spectrum, median survival should take this early stage of diagnosis into account as well as later stages of the disease. Therefore, since our growing understanding of the natural history of breast cancer suggests that the duration of time from in situ carcinoma to frank invasive carcinoma varies from 5 to 20 years, depending upon cell type(2,6-20,34-35), and since the median survival of treated, invasive carcinoma is 10 years, we believe that it is not unreasonable to postulate a median survival time for the full spectrum of the disease, from 10 to 16 years. Since 85 to 90 percent of carcinomas are of ductal origin, which is the more rapidly evolving cancer, a weighted average of 6 years latency is added to the 10 years median survival of clinical cancers in order to arrive at a disease duration of approximately 16 years. The mean survival time may in fact be longer, but it almost assuredly is not shorter.

Thus, it can be seen in Table 3 that the actual prevalence rate of cancers which we found to be present in all decades is bracketed by the predicted number of prevalent cancers. The only exception is in the age groups 35-44, where the number of cancers found is lower than the predicted outcome rate. We do not think this means that there are fewer cancers extant in this decade in our population, but rather this is a reflection of the relative difficulty in achieving a diagnosis of early carcinoma of the breast in younger women.

In addition, this concept of disease duration combined with known annual incidence figures for cancer in all stages strongly supports the following concepts. Cancer in situ is frank cancer. Cancer in situ is irreversible disease which will become expressed at some time in the future. The ideal time to attack breast cancer is at this early stage.

As a result of the observations noted above, this particular patient sample being evaluated is probably fairly representative of the general population vis-a-vis carcinoma of the breast. Undoubtedly new carcinomas will be found in this population. Hence, if this concept of the disease is correct, i.e., that carcinoma evolves from a continuum or a spectrum of premalignant disease, then new cancers should develop at a reasonably predictable rate, and some cancers which were missed by current techniques will come to light over the next several years as a result of screening at appropriate intervals.

Furthermore, if one presumes that the cross-sectional sampling of this population of women will be representative of events occurring longitudinally in time, the sum of the prevalent cancers in this population should approximate the number of cancers which would be predicted to develop in a population of 1,000 women. If it is correct that one out of 15 women currently alive in this country today will develop carcinoma of the breast, and that 95 percent of these cancers will develop after the age of 35, then 63.3 cancers could be expected in a population of 1.000 women. Our method of predicting prevalence would indicate from 51.24 to 73.44 cancers will develop. We have actually found prevalent cancers at a rate of 56.51 per thousand. Thus, again, these data would suggest that, if anything, the number of prevalent cancers discovered is lower than the prevalent cancers which actually exist in this population, and further, the cross-sectional sample may well be reasonably predictive of longitudinal events.

It is postulated that the prevalence rate for any decade can be used as a model for predicting longitudinal events to occur within each decade. This concept remains to be borne out by further longitudinal study, but it presents us with a model which seems reasonable. For example, as indicated in Table 4, this model would predict that in the 10 years of followup of women age 35-44, one would expect to find 1.58 minimal breast cancers per thousand by mammography alone. This would translate into 6 minimal breast cancers over the 10-year span in this population group of 3,792 women. In the second year of screening, 2 such cancers have already been proven by biopsy in this age group. It is not unreasonable to presume that 4 more such cancers would be found over the next 9 years, if we were to continue screening for that interval.

BENEFIT/RISK DISCUSSION

Table 5 indicates the risk of radiation induced cancers per thousand population on annual screening for 5, 10, 20, and 30 years. The latent period presumed for development of these cancers is 10 years, and a plateau occurs at 30 years(28). These calculations for risk presume a population of women that remains constant for the entire 30 years at risk. This position is extremely conservative and unduly magnifies the risk estimate. Based on the assumptions made previously, benefit-risk ratios for detection of minimal cancer found by mammography alone have been calculated for several models of screening (Table 6). For this particular evaluation, screening was assumed to begin at age 35 and continue for 10, 20, or 30 years. It should be noted clearly that benefit is based on the cumulative number of minimal breast cancers that would be expected to be detected by mammography alone in each decade. Since risk is calculated on a cumulative basis, benefit likewise should be calculated on a cumulative basis.

Assuming the very worst of circumstances, i.e., upper bounds of risk, and that no further cancers other than the prevalent cancers which we have already detected are found, benefit still exceeds risk, but by a relatively small number between the ages of 35-44. For all other age ranges the benefit risk ratio indicates a substantial positive yield. A reasonable central bounds ratio doubles benefits. Continuing screening for an added 10 years increases benfits by 70 percent. Assuming the reasonableness of the modeling factors given previously, it should be noted that at no time does the cumulative risk equal or exceed the cumulative benefit even using the most conservative risk model. However, if our projections about incidence are reasonable, then therapeutic ratio can only increase, by virtue of the addition of prevalence to incidence. Forthermore, in this and in all subsequent calculations, no accounting has been made for decline in number of patients due to death from other causes. This change would lower the net cumulative absolute cancer risk, and should be taken into consideration.

In order to assess the potential impact of mammographic screening on survival versus impact of mammographic screening on patient mortality, the data in Table 7 were derived. The assumptions given previously remain constant for both groups of patients. For mortality calculations a latent period of 10 years is presumed(28,29). We have further presumed that mortality effect in terms of person years lost should be based on the mean survival expected for that decade, rather than using a maximum plateau period of 30 years. Again, this approach seems conservative. The gain in person years calculated for each decade does not include accumulated projected breast cancers detected by mammography alone. Rather, it is based on the survival of patients with expected minimal breast cancers detected within that decade. Person years lost does include cumulative radiation and is unduly magnified, again a conservative position. When all decades are summed, since the net person years gained ranges from 154-219/1000, mammography used in this manner on a continual lifetime of screening would contribute significantly more person years than it would cause to be lost.

The role of mammography in screening can also be evaluated by comparing the net effect of screening with mammography alone versus screening with physical examination as used in the Cincinnati Breast Cancer Detection Center, and the use of physical examination as carried out in metropolitan Cincinnati. When evaluating Table 8, it should be noted that the yield for minimal breast cancer by physical examination at the Breast Cancer Detection Center in Cincinnati is a result of a very aggressive approach and a high rate of reommended biopsy. In the surveillance system existing prior to this screening center, only 1.7 percent of all carcinomas detected have been minimal cancer. We would venture that nationally this figure is representative for minimal breast cancer detection by physical examination alone.

Table 3. Prevalent cancers found in this screening population vs. the cancers predicted

	35-44	45-54	55-64	65-75	TOTAL
Cancers Found/1000 Patients Studied	3.95	12.52	15.8	20.2	56.51
Predicted Prevalent Cancers Per 1000 Patients	5.9 - 6.86	11.67 - 16.10	15 - 22.50	18.67 - 27.98	51.24 - 73.44
# Cancers Found/Total # Patients	15/792	46/3673	32/2019	18/890	111/10374
Mean # Cancers Predicted/ Total # Patients	24/3792	51/3673	38/2019	21/890	134/10374
% of Cancers - Minimal (All)*	67%	39%	28%	28%	
% of Cancers - Minimal + Stage I	73%	67%	94%	81%	

*Minimal cancer as defined by Gallager references 9, 10, 11.

Table 4. Rate of minimal cancers/1,000 modality

	35-44	45-54	55-64	65 +	TOTAL
Mammo Alone Pos. Minimal	1.58	2.72	3.96	3.37	11.63
PE Alone Pos. Minimal	0.53	1.09	.49	2.25	4.36

Table 5. Risk of induction of cancer by mammography by annual screening per rad absorbed

# Years Annual Screening	# Pts.	Cumulative Person Rad Years Assuming No Recovery	Number Of Induced Cancers/1000 Patients UNSCEAR (A)	BEIR (B)	WASH 1400	Cumulative Person Rad Years (D) Assuming Partial Recovery	UNSCEAR	BEIR	WASH 1400
5	1000	$\frac{1000\ (5+4+3+2+1) + (25 \times 5)}{10^6}$	.098	.84	.42	$\frac{1000\ (5+4+3+2+1) + (25 \times 1)}{10^6}$	.03	.24	.12
10	1000	$\frac{1000\ (10+9 \ldots 1) + (20 \times 10)}{10^6}$	.18	1.53	.765	$\frac{1000\ (10+9 \ldots 1) + (20 \times 1)}{10^6}$	.05	.45	.23
20	1000	$\frac{1000\ (20+19 \ldots 1) + (10 \times 20)}{10^6}$	.29	2.46	1.23	$\frac{1000\ (20+19 \ldots 1) + (10 \times 1)}{10^6}$	.15	1.32	.66
30	1000	$\frac{1000\ (30+ \ldots 1)}{10^6}$	.33	2.79	1.4	$\frac{1000\ (30+29 \ldots 1)}{10^6}$	.33	2.79	1.4

RISK ESTIMATES

A UNSCEAR (19) = .7
B BEIR (28) = 6
C WASH 1400 (29) = 3
D (Assuming 80% Recovery) WASH 1400 page G-8

Table 6. Benefit risk ratio for screening 1,000 women beginning at age 35 - based on projections from Cincinnati BCDC (high - med - low based on Table 5)*

DECADE OF FOLLOW-UP

	35-44			45-54			55-64			65+
Total Cancers Expected To Find / 1000 Pts. Per Decade	3.95			12.25			15.8			20.2
Cancers Induced Per 1000 Screenees	U.	C.	L.	U.	C.	L.	U.	C.	L.	
10 Yrs.	1.53	.77	.05							
20 Yrs.				2.46	1.23	.15				
30 Yrs.							2.79	1.4	.33	
#Minimal Cancers / 1000 Expected by Mammo Only	1.58			2.72			3.96			
#Minimal Cancers / 1000 +Stage I by Mammo Only	1.58			5.7			7.42			
Benefit / Risk (Cumulative)	U.	C.	L.	U.	C.	L.	U.	C.	L.	
	1.03	2.05	31.6	1.74	3.49	28.6	2.96	5.9	25	
							MINIMAL + STAGE I**			
							4.2	8.35	35.5	

*All calculations assume the population of 1,000 women remains constant for 30 years to receive an examination every year.

**Cumulative Benefit Includes Stage I + Minimals In This Decade + Minimals Of All Prior Decades

U = Upper bound estimate for induced cancer
C = Central bound estimate for induced cancer
L = Lower bound estimate for induced cancer

Table 7. Patient years gained as a result of screening beginning at age 35 (assuming 1,000 patients and no deaths due to other causes)

E	MEAN LIFE EXPECTANCY	SURVIVAL	PYG	BOUNDS FOR INDUCED CANCER U.	C.	L.	MORTALITY	PYL U.	C.	L.	NET PERSON YRS GAINED U.	C.	L.
44	39 Yrs.	1.58x80%x39	49.2	1.53	.77	.05	.50x29x1.53 .50x29x.77 .50x29x.05	22.2	11.2	.73	27	38	48.5
54	30	2.72x.80x30	65.3	2.46	1.23	.15	.50x20x2.46 .50x20x1.23 .50x20x.15	24.6	12.3	1.5	41	53	63.8
64	22	3.96x.80x22	70	2.79	1.4	.33	.50x12x2.79 .50x12x1.4 .50x12x.33	17	8.4	2	53	62	68
	15	3.37x.80x15	40	2.79	1.4	.33	.50x5x2.79 .50x5x1.4 .50x5x.33	7	3.5	.83	33	36.5	39
al			224.5					70.8	35.4	5.1	154	189.5	219.3

NET PERSON YEARS GAINED/MILLION PERSONS:

154,000	(Upper Bounds)
189,500	(Central Bounds)
219,300	(Lower Bounds)

PYG = Person years gained

PYL = Person years of life

Table 8. Risk benefit of screening every 10 years with mammography only vs. screening by physical examination (PE) only

	Mammography Screening AGE 35 - 44	AGE 45 - 54	WASH-1400(29)	BEIR(28)	AGGRESSIVE PE SCREENING (MAMMO NOT DONE) 35 - 44	 45 - 54	EXTANT PE 35 - 44	 45 - 54
MINIMAL CANCER DISCOVERED (cases/1000 persons)	2.1	3.8	----	----	1.05	2.2	.07	.21
ESTIMATED CANCERS INDUCED (cases/1000 persons)	----	----	.77	1.53	0	0	0	0
PERSON YEARS GAINED FOR MINIMAL CANCERS DISCOVERED	65	90	----	----	32.	68.	2.	5
PERSON YEARS LOST BY ESTIMATED CANCERS INDUCED	----	----	11.2	22	----	----	----	----
NET PYG FOR 10 YEARS OF SCREENING	WASH 1400 54 BEIR 33	WASH 1400 79 BEIR 68	----	----	32.	68.	2.	5
** PYG - MAMMO / PYG - EXTANT PE — WASH 1400	54/2.=27	79/5=16						
** PYG - MAMMO / PYG - EXTANT PE — BEIR	33/2.=16	68/5=14						
PYG-MAMMO / PYG-AGGRESSIVE — WASH 1400	54/32.=1.7	79/68=1.1						
PYG-MAMMO / PYG-AGGRESSIVE — BEIR	33/32.=1	68/68=1						

*Includes all minimal cancers found by either modality

** These ratios represent the effect of the upper and central bounds risk rates on PYG as a result of mammography vs extant and aggressive physical examination

The information contained in Table 8 is based upon a presumption of screening two sets of populations for 10 years. It does not presume annual screening for a 20-year period. It is at once apparent that net benefit of mammography when compared with physical examination as it has been generally practiced in Cincinnati is from 14 to 27 times as effective using either central or upper bounds limits for induced cancer calculation. When physical examination is used aggressively, as in the Cincinnati Breast Cancer Demonstration Project, the effective ratio of mammography/PE is not quite so apparent.

However, since these two modalities are not identifying the same lesions, one should not be subtracting patient years gained one from the other. Rather, in point of fact, these are mutually additive modalities. This concept is exceedingly important and is demonstrated in Table 9. Here one can see that by screening a patient population aged 35 to 44 for 10 years, the net patient years gained by finding minimal breast cancers by mammography along ranges from 27 to 38. The net patient years gained by adding this to the 32 patient years gained for minimal breast cancers found by physical examination in this same population group is 59 to 70 years. Since this differential yield on physical examination and mammography exists at every decade, if we presumed the model described earlier, a net cumulative benefit for both modalities can be shown.

It may be argued that we are not justified in assessing cumulative maximal benefits, rather than assessing incidental benefit only. It is our belief that evaluating cumulative risk versus annual incidence is an incorrect comparison. Since conversion rates from premalignant and early malignant disease into cancer is not yet known, annual screening may be necessary to maximize impact on early discovery. Spreading out intervals and reducing frequency may reduce the number of minimal lesions found. Therefore, cumulative risk must be compared with cumulative benefit over the time interval being evaluated. Since cumulative risk begins with initial irradiation, cumulative benefit should include prevalent lesions discovered as well, although we have not done so for these calculations. As long as that ratio is in excess of one, the study can be medically justified.

Although upper, central, and lower bounds have been considered here in calculation of absolute risk, there are cogent arguments against adopting either extreme position. One could make a very strong case for an absolute risk factor of 3 or 6 as representing a reasonably authoritative or even reasonably conservative point of view. While the UNSCEAR figure of 0.7 as quoted in WASH-1400(29) is low, in relation to BEIR estimates, it represents a calculation only from observed data points but does not include the 0 point. BEIR calculations reflect axiomatically the zero point in their interpolated risk estimates.

For us to make the assumption that there is no repair from low-dose, highly fractionated irradiation, may be unduly conservative. "Both BEIR and United Nations caution that this linear hypothesis is likely to overestimate the risk for lower doses. . . and that in cases of low exposure, it cannot be ruled out that the risk may be actually zero."(29) It is, therefore, conceivable that some repair occurs following low-dose radiation on the order of 1 rad, protracted over a year's interval.

SUMMARY

It is apparent from the data presented herein that screening of younger women is not yet maximally efficient. Nevertheless, the data quite clearly also show that if any benefit is to be achieved by screening, particularly in younger women, it can be reached by an aggressive approach to both physical examination and mammography, and the use of low-dose, effective, radiographic techniques.

Table 9. Patient years gained by screening with mammography and physical examination: minimal cancers found by each modality

	35-44	
	BEIR	NU. REG
Net PYG by Finding Minimal Cancers on Mammography alone*	27	38
Net PYG by Finding Minimal Cancer on all aggressive PE (extant not included)		32
Total PYG by Finding Both	59	70

*Does not include minimal cancers also found on physical examination

The data here do not make an overwhelming case for mass, annual, lifetime screening of all younger women. It may even be that subsequent screening after an aggressive initial approach such as ours will demonstrate the yield of cancer detected will be so low that very infrequent screening intervals will be needed. If it were so, it is a consummation devoutly to be desired.

There is a need for caution on all sides. We must all admit that we are dealing with imponderables which have not yet been resolved. On the one hand, failure to consider possible risk could lead to more problems than solutions, particularly if "curable" lesions are not found. On the other hand, there is equal responsibility necessary for those who decry the use of mammography. If there is an opportunity to offer a significant number of patients, harboring a potentially fatal disease, freedom from that disease, we must take care to be certain that in our zeal to protect the unwary from the possible carcinogenic effects of low-dose radiation, we do not protect them from potential cure. Can the case be overstated on both sides?

These data we present here, we think, indicate that there is no need for panic and irrational fear of the screening process, so long as the conditions of screening are reasonably well-controlled. Alternate stratagems and frequencies of screening by age groups and risk categories will almost certainly evolve from the continued operation of the Breast Cancer Demonstration Projects.

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THE ISSUES: BENEFIT - RISK IN MAMMOGRAPHY

Richard P. Chiacchierini and Frank E. Lundin
Bureau of Radiological Health, FDA
(Presentation made by Dr. Chiacchierini)

Introduction

The use of x-ray mammography in mass screening for breast cancer in asymptomatic women presents a special problem in radiological health. Mammography has the potential to detect some breast cancers before they become clinically palpable. It also has the potential to affect the radiosensitive breast in a manner which could lead to cancer induction. Because of the double-edged nature, a balance must be obtained between the benefit of early detection and treatment and the risk of a radiation induced breast carcinoma later in life.

The major purpose of this paper is to use the life table model to evaluate the risk/benefit balance as a function of annual radiation dose. In a previous paper *(1)* a mathematical model of the life table was presented as a means to analyze the short-term and lifetime implications of annually screening for breast cancer by physical examination and mammography. That method will be briefly discussed here for reference and the results of that study will be reviewed. As in the previous study, annual screening examinations will include both mammography and physical examination and the age at first screening will vary. The analyses depend on two hypothetical breast cancer radiation risk models and one estimate of beneficial mortality reduction. Studies are currently in progress to analyze the risks and benefits from doses other than those presented here and levels of mortality benefits which might be related to current or future technology.

Materials and Methods

An abridged life table model (i.e., one in which ages are grouped into 5 year intervals) was used to estimate the effects of annually screening for breast cancer, with a procedure that includes x-ray mammography, on a hypothetical population of women who are followed through the life table until all have died. The estimations procedure involves the application of the natural risks, and the possible risks and benefits from annual screening procedures to a population of women who enter the life table at exactly 35 years of age and who begin annual screening at different exact ages: 35, 40, 45, and so forth. The use of the life table model is intended to estimate the effect on breast cancer mortality of annual screening starting at different ages and continuing to 85 years of age after which participation is expected to be nil.

A flow chart of the calculations that are necessary to estimate the risks and benefits is given in figure 1. A detailed discussion of the necessary calculations is given in Appendix I.

Base information from several sources was obtained and simplifying assumptions were made in the course of this study. The natural risk of death from all causes and the average time lived in each interval by those who died were obtained from the Life Table of the United States - 1973 (U.S. Vital Statistics

Monthly Report, February 10, 1975) *(2)*. Age specific total and breast cancer mortality rates were from the Vital Statistics of the United States - 1971 (Part B - Mortality, 1975) *(3)*. The observed and derived constants used are given in table 1. These data allowed the calculation of an estimated number of women in each 5-year interval who die from all causes and the number naturally dying of breast cancer in the absence of any risk or benefit from screening. Any effects from the current use of mammography screening in the general population are considered negligible in this analysis.

To estimate the number of deaths from breast cancer attributable to radiation, a risk model is assumed incorporating both the total dose received and the latent period. For purposes of this report, the risk estimates per rad of absorbed dose given in the National Academy of Science Committee on the Biological Effects of Ionizing Radiation report are assumed *(4)*.

The BEIR report gives two types of risk estimates each of which has been incorporated separately into the life table model. Illustration of the two risk models is given in figure 2. The first type, the absolute risk model, is an additive model which estimates the excess cancer risk observed in an exposed group by subtracting the risk of cancer in the controls from that in the exposed population. The second type, the relative risk model, is a multiplicative model obtained as the ratio of the risk of cancer observed in the exposed population to that observed in the controls. The absolute risk model estimates that 6 x 10^{-6} person-year-rem are added to the natural breast cancer incidence between 10 and 30 years after exposure. The relative risk model estimates that the natural incidence is increased by 0.8%/rem-year over the same time period. The estimates of radiation induced cases or deaths based on the absolute risk model are considerably lower than those based on the relative risk model but there is no sound basis at this time to determine which of the two methods is more appropriate for breast cancer. Consequently in this report, both methods have been used and the results are presented for both risk models.

The dose to each breast is an annual average dose made up of the sum of the average depth doses from the films that comprise an annual screening examination. It is given in rads rather than rem because, for x irradiation, the two terms are equivalent.

The BEIR report (1972) indicated that the average latent period for induction of breast cancer was from 15 to 20 years after exposure. It further indicated that an estimated range of latency shown in figure 3 extends from 10 to 30 years after exposure, though the upper limit is based more on the period of followup in the reported studies than on biological factors. Using these data and the assumed average rads per screening exam, an effective dose is calculated such that the radiation dose is considered effective in the induction of breast cancers only between 10 and 30 years after exposure. The addition of all such doses from all previous annual exposures constitutes the effective dose for each single year of age. In the abridged life table the effective dose for each 5-year interval is taken to be the mid-interval accumulated dose.

The complexity of the effective dose computation is illustrated in the following example. Suppose a woman receives a depth dose of 5 rads to each breast per year between the ages of 35 and 40. Her total accumulated dose would be 25 rads but her mid-interval dose for the 5-year period is 12.5 rads. This dose would not be effective for elevating the breast cancer risk until the interval beginning with age 45 and the risk would remain elevated until the end of the 5-year interval beginning at age 60. If she receives an additional 5 rads per year between 40 and 45 years of age, her effective dose would be 12.5 rads for the interval beginning at age 45: 37.5 rads for the three intervals beginning at ages 50, 55, and 60, respectively; and 25 rads for the 5-year interval beginning at age 65. Additional doses are accumulated in the same manner.

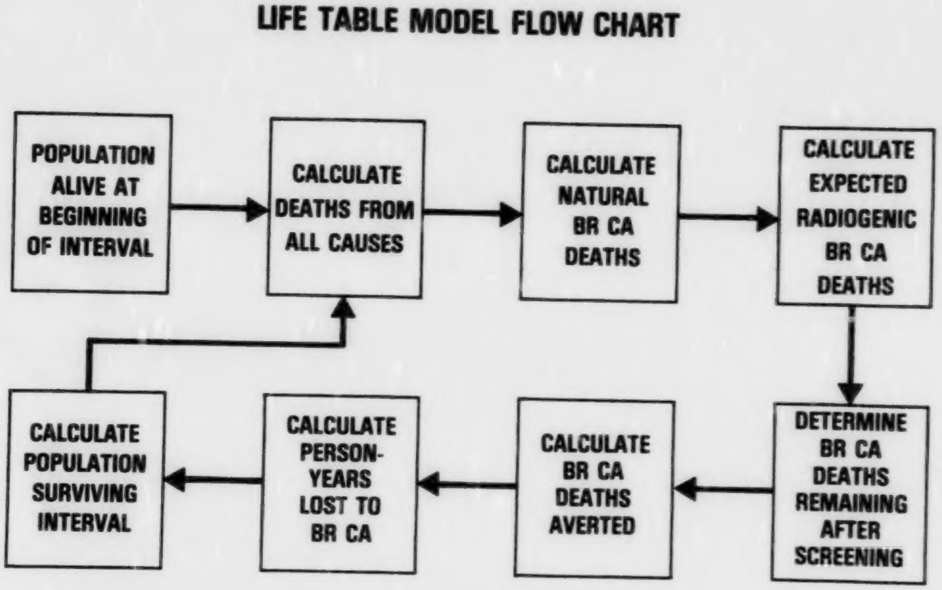

LIFE TABLE MODEL FLOW CHART
POPULATION ALIVE AT BEGINNING OF INTERVAL
CALCULATE DEATHS FROM ALL CAUSES
CALCULATE NATURAL BR CA DEATHS
CALCULATE EXPECTED RADIOGENIC BR CA DEATHS
DETERMINE BR CA DEATHS REMAINING AFTER SCREENING
CALCULATE BR CA DEATHS AVERTED
CALCULATE PERSON-YEARS LOST TO BR CA
CALCULATE POPULATION SURVIVING INTERVAL

Figure 1.

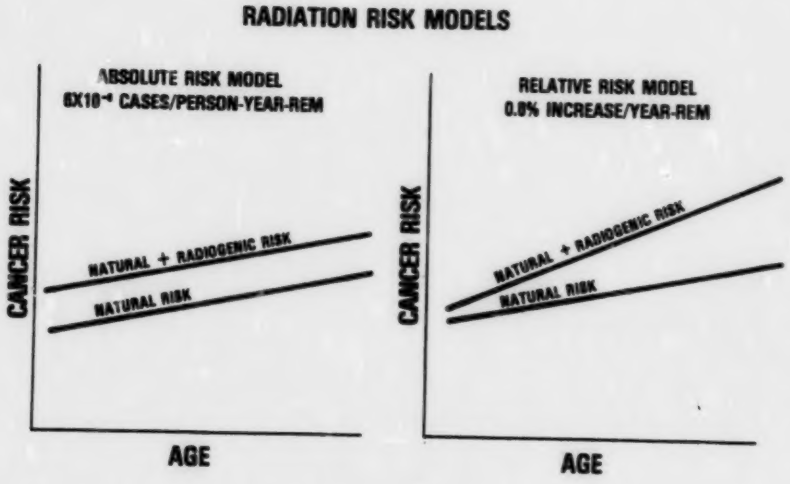


Figure 2.

Table 1. Life table observed and derived constants

Exact Age of Beginning of Interval X_i	Probability of Death from all Causes in Interval q_i	Age-Specific Mortality Rate for Breast Cancer $M_{i\delta}$ ($X10^{-5}$)	Age-Specific Total Mortality Rate M_i ($X10^{-5}$)	Fraction of Interval Lived by those Who Died a_i	Age-Specific Mortality to Incidence Ratio $M_{i\delta}/I_{i\delta}$	Years of Life Lost z_i
35	0.0084	13.9	169.3	0.532	0.261	40.2
40	0.0130	26.4	260.9	0.533	0.257	35.6
45	0.0200	44.7	404.4	0.533	0.287	31.2
50	0.0287	61.3	582.1	0.528	0.364	26.9
55	0.0436	76.1	889.8	0.530	0.404	22.8
60	0.0625	79.3	1287.3	0.529	0.357	18.9
65	0.0910	90.2	1901.7	0.528	0.396	15.3
70	0.1468	98.3	3155.6	0.525	0.386	11.9
75	0.2366	122.2	5339.4	0.519	0.421	9.1
80	0.3450	135.8	8343.2	0.499	0.457	6.9
85	1.0000	157.1	16234.0	0.388	0.521	3.6

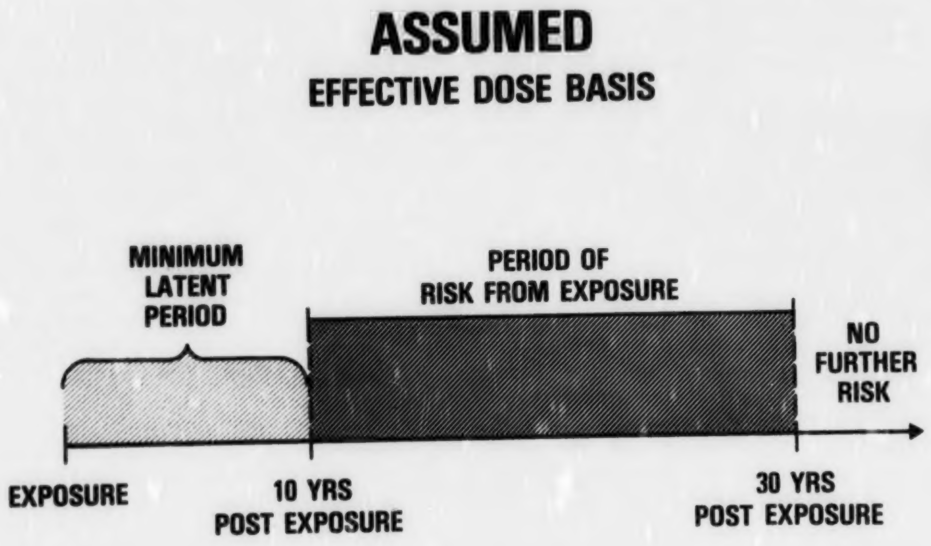


Figure 3.

The risk estimates from the BEIR report (1972) are given in terms of breast cancer incidence and it was necessary to convert them to breast cancer mortality. Using the age specific breast cancer incidence rates from the Third National Cancer Survey *(5)* and the breast cancer mortality rates mentioned previously, a mortality to incidence ratio was formed which, when multiplied by the calculated radiogenic incidence, yields the estimated number of breast cancer deaths.

Information used in this study, on the benefits of a combined screening regimen, including both mammography and clinical examination, were obtained from a large clinical trial begun in 1963. Shapiro et al. *(6)* present the results of the screening procedure used in this study of 60,000 women aged 40 to 64 enrolled in the Health Insurance Plan of Greater New York (HIP). The data from the HIP study which are factored into the model presented here are the mortality improvement for each of three age groups (< 50, 50-59, ≥ 60).

The assumptions necessary for use of these data are as follows: that the improvement in 5-year mortality reported by Shapiro, et al. *(6)* remained a permanent improvement; that the age specific mortality improvement experienced in the HIP study could be extended to the United States female population; that the mortality reduction observed in the HIP study for the 40-49 and the 60-69 year classes applied to the 35-40 and over 69 year age classes respectively; and that the screening procedure would not expose or benefit anyone over 85 years of age.

A further complication in the dosimetry follows from the fact that some women in the HIP study in each age interval were not screened at all and others were not screened annually. A dose adjustment factor was computed based on the age specific participation rates in the screening program described by Shapiro et al. *(6)*. This factor was 0.5416 for those below age 50, 0.5129 for those

50-59 years of age, and 0.4779 for those 60 years of age and over. In the dose example given previously this change would imply that the 12.5 rads would be reduced to 6.8 rads as an average dose to the whole population. In reality, 54.2 percent of the women received 12.5 rads but it makes no difference to the risk model used whether half as many women receive the whole dose or the whole population of women receive half the dose. The mathematical result is the same.

The major benefit from screening with both mammography and physical examination observed in the HIP study was an age-dependent improvement in breast cancer mortality. This improvement is factored into the life table model by multiplying the total number of breast cancer deaths in any interval, obtained by summing the natural and radiogenic deaths, by the ratio of the mortality observed in the HIP study group to the mortality of the controls. This calculation yields the estimated number of women dying from breast cancer in the interval in spite of the screening procedure. The gross number of lives saved is then calculated by subtracting the remaining breast cancer deaths from the total breast cancer deaths in the interval. An inherent assumption here is that radiogenic and natural cancers cannot be distinguished from each other, particularly as regards tumor behavior.

Finally, the number of person-years lost by those who died from breast cancer in each 5-year interval is computed by multiplying the number of breast cancer deaths remaining by the expectation of life.

To summarize the workings of the life table model, within each 5-year age interval, the number of women dying from all causes and the sub-class dying of natural breast cancer are determined. The effective dose is then utilized to estimate the number of women who would die from radiation induced breast cancer in the absence of a screening benefit. The total breast cancer deaths are obtained by summing the natural and radiogenic components. The corresponding number of breast cancer deaths that are expected in spite of screening is estimated by multiplying the total breast cancer deaths by the ratio of the HIP study to control age-specific mortality rates. This ratio is 1.0 for ages 35-49, 0.46 for ages 50-59, and 0.68 for age 60 and over. The gross number of lives saved is then obtained by subtracting the deaths which remained from the number that were expected in the absence of a risk or benefit.

Results

In this section two examples of a life table derived from our model are given so that the reader may become familiar with the manner in which the hypothetical population is followed. Following the examples a series of comparisons will be given to indicate the effect of reduction in dose on the number of breast cancer deaths averted and the number of person-years gained by implementing the combined screening program in the general population.

In table 2, a life table is presented in which no screening regimen has been administered. The data in this table constitute a baseline for comparison with other modeled life tables to which screening has been added. Note that we begin with 100,000 women at the exact age of 35 years. In the 5 years after their 35th birthday, 840 women died from all causes and 69 died from breast cancer. Since no screening has been experienced by this population, the effective dose is zero; hence, no radiogenic cancers appear and no lives are saved. By deleting the 840 women who died, we enter the next row of the life table with 99,160 women at the exact age of 40 and we continue in this manner until all women in the population have died.

Note that of the 100,000 women entering the life table at the exact age of 35, 3,040 are expected to die naturally from breast cancer. This constitutes 3

Table 2. Model life table showing the natural breast cancer deaths without screening intervention

Exact Age at the Beginning of Interval	Number Alive at Start of Interval	Number of Deaths from all Causes in Interval	Natural Breast Cancer Deaths*	Effective Dose (rads)	Radiogenic Breast Cancer Deaths*	Total Br Ca Deaths	Number of Lives Saved	Person-Years Lost in Interval Due to Br Ca
35	100000	840	69	0	0	69	0	2774
40	99160	1289	130	0	0	130	0	4628
45	97871	1957	217	0	0	217	0	6770
50	95914	2753	290	0	0	290	0	7801
55	93161	4062	347	0	0	347	0	7912
60	89099	5569	343	0	0	343	0	6483
65	83530	7601	361	0	0	361	0	5523
70	75929	11146	347	0	0	347	0	4129
75	64783	15328	351	0	0	351	0	3194
80	49455	17062	278	0	0	278	0	1918
85	32393	32393	307	0	0	307	0	1105
TOTAL	-----	100000	3040	---	0	3040	0	52237

*Breast cancer deaths expected to occur in the absence of screening benefit.

percent of the population at age 35 and is as expected in agreement with the breast cancer mortality in the United States female population. Note also that the number of breast cancer deaths rises sharply between ages 35 and 55 and then remains relatively level even though the size of the population at risk is declining. It should be understood that the breast cancer deaths are included in the deaths from all causes.

In the second life table example, shown in table 3, the effect of both risks and benefits from a combined screening procedure, which includes mammography and physical examination, is illustrated. Screening begins at age 35 and the dose to each breast per annual examination is 5 rads. In this example the absolute radiation risk is utilized. Note that when the HIP age specific mortality reduction is used, we estimate grossly that 980 deaths are averted by screening, but that none occur below age 50. A total of 292 deaths are expected to be caused by mammography under the absolute risk model at the assumed dose. In this table also the deaths from all causes includes all breast cancer deaths estimated to occur in each interval.

Model life tables similar to table 3 have been constructed for cohorts of women aged 35 assuming that screening was begun alternatively at ages 35, 40, 45, 50, 55, or 60 under both the absolute and relative risk models for 1, 5, and 10 rad doses. A schematic of these cohorts is given in figure 4.

In the graphs that follow, the data are given in two ways; breast cancer deaths averted and person-years gained. The net breast cancer deaths averted are calculated by subtracting the number of breast cancer deaths remaining in a given life table in spite of screening from the number that would have occurred without screening at any age (3040 from table 2). The person-years gained is calculated in a similar manner by subtracting the total person-years lost from breast cancer deaths in the presence of screening in a given life table from those lost in the absence of any screening (52,237 from table 2).

In figure 5, the estimated number of breast cancer deaths averted are shown by age at first screening when the HIP age specific mortality reduction, absolute radiation risk, and 10 rads per breast annual dose are assumed. Note that this model estimates that the maximum benefit of 666 lives saved is attained when screening is begun at age 50.

In figure 6, the same type of data is portrayed for 5 rads annual dose to each breast using the same benefit and risk assumptions. The arrows denote the values obtained from 10 rads annual dose. Note that once again the maximum benefit is estimated to be reached by initiating the annual combined screening program at 50 years of age. Furthermore, note that regardless of the age at first screening, the number of lives saved at the lower dose of 5 rads is larger than the number saved at 10 rads.

In figure 7, the breast cancer deaths averted under the absolute radiation risk and HIP age-specific benefit assumptions are presented for an annual dose to each breast of 1 rad. Similarly the maximum benefit of 850 deaths averted is estimated to occur by beginning screening at age 50. In comparison with the higher doses (indicated by the arrows), the number of deaths averted at 1 rad annual dose greatly exceeds those averted at higher doses at all starting ages.

In figure 8, the estimated number of person-years gained are presented assuming HIP age-specific benefit, absolute radiation risk and three annual breast doses. The information portrayed here corresponds to that given in figure 7. Note that for all three doses, the maximum number of person-years are estimated to be gained by beginning screening at age 50. As indicated by the deaths averted, the pattern of lower doses leading to higher benefits is

Table 3. Model life table estimating risks and benefits of screening begun at 35 assuming absolute risk at 5 rads per breast per annual examination

Exact Age at the Beginning of Interval	Number Alive at Start of Interval	Number of Deaths from all Causes in Interval	Natural Breast Cancer Deaths*	Effective Dose (rads)	Radiogenic Breast Cancer Deaths*	Br Ca Deaths Remaining After Screening	Number of Lives Saved	Person-Years Lost in Interval Due to Br Ca
35	100000	840	69	0.0	0	69	0	2774
40	99160	1289	130	0.0	0	130	0	4628
45	97871	1963	217	6.8	6	223	0	6958
50	95908	2606	290	20.3	21	143	168	3847
55	93302	3897	348	33.8	37	177	208	4036
60	89405	5507	344	46.7	43	263	124	4971
65	83898	7553	362	52.7	50	280	132	4284
70	76345	11124	349	51.1	42	266	125	3165
75	65221	15343	353	49.5	36	265	124	2412
80	49878	17137	280	48.7	28	209	99	1442
85	32741	32741	310	47.9	29	339	0	1220
TOTAL	-----	100000	3052	----	292	2364	980	39737

*Breast cancer deaths expected to occur in the absence of screening benefit.

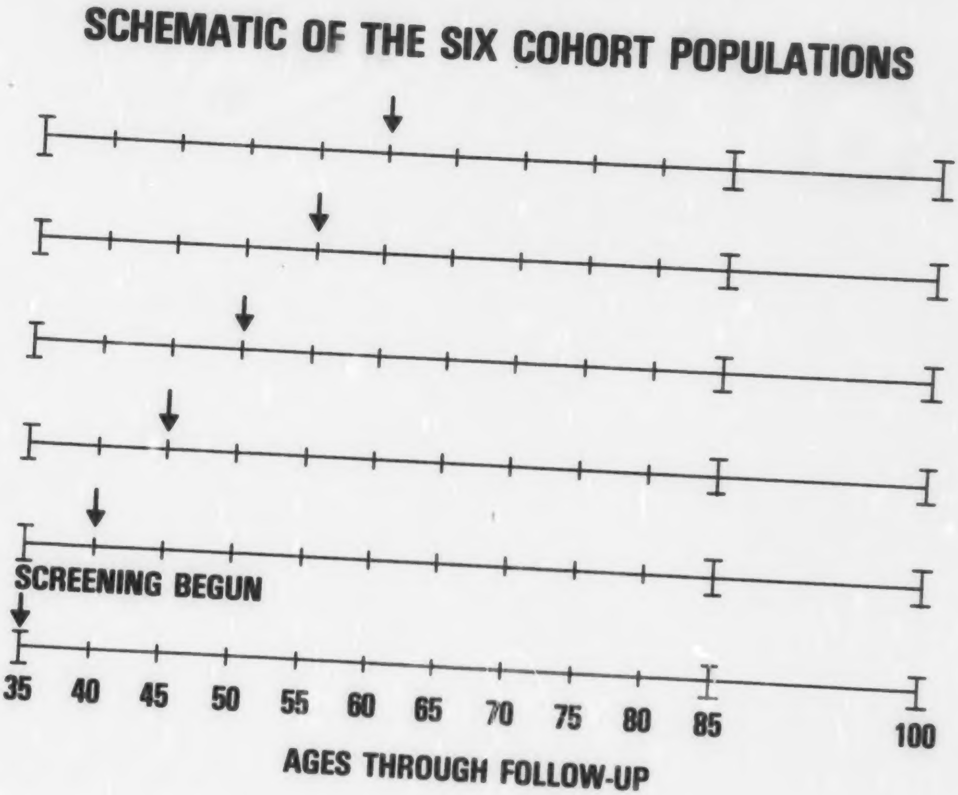
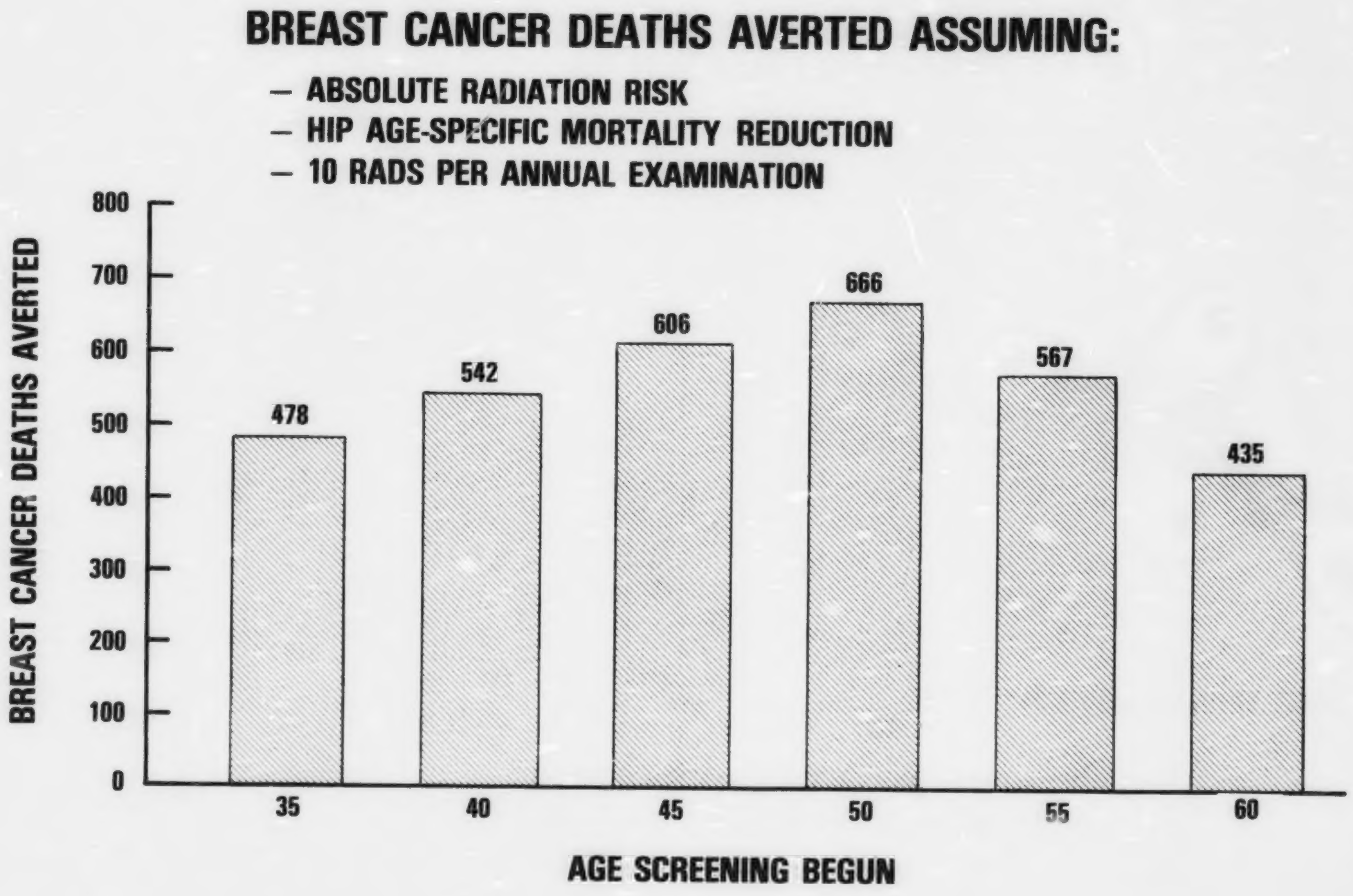


Figure 4.

indicated here as well with the person-years gained for the annual dose of one rad exceeding those gained for both the 5 and 10 rad levels.

Figure 9 indicates the breast cancer deaths averted assuming the three annual doses (1,5, and 10 rads), the HIP age-specific benefit and the relative radiation risk. While the maximum number of lives were saved by initiating screening at age 50 for both 1 and 5 rads, the maximum benefit is not attained until age 60 or over when 10 rads is assumed. Though the age relationship differs under this risk model, the dose relationship is preserved; i.e., of the three doses considered, the highest level of benefit at each starting age is attained with 1 rad annual dose followed by 5 rads with 10 rads giving the lowest levels. In fact, for the relative radiation risk, the life-table model predicts a net deficit of lives saved by beginning annual screening below age 50.

In figure 10, the person-years gained corresponding to the deaths averted in figure 9 are given. Note that considering the relationship between person-years and age for the 10 rad dose results in a shift in the maximum value. All three doses exhibit the maximum person-years gained when the age at first screening is 50. Again the 1 rad dose yielded more person-years gained than did 5 rads which resulted in a greater gain than 10 rads.


BREAST CANCER DEATHS AVERTED ASSUMING:
– ABSOLUTE RADIATION RISK
– HIP AGE-SPECIFIC MORTALITY REDUCTION
– 10 RADS PER ANNUAL EXAMINATION
BREAST CANCER DEATHS AVERTED
800
700
600
500
400
300
200
100
0
478
542
606
666
567
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35
40
45
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55
60
AGE SCREENING BEGUN

Figure 5.

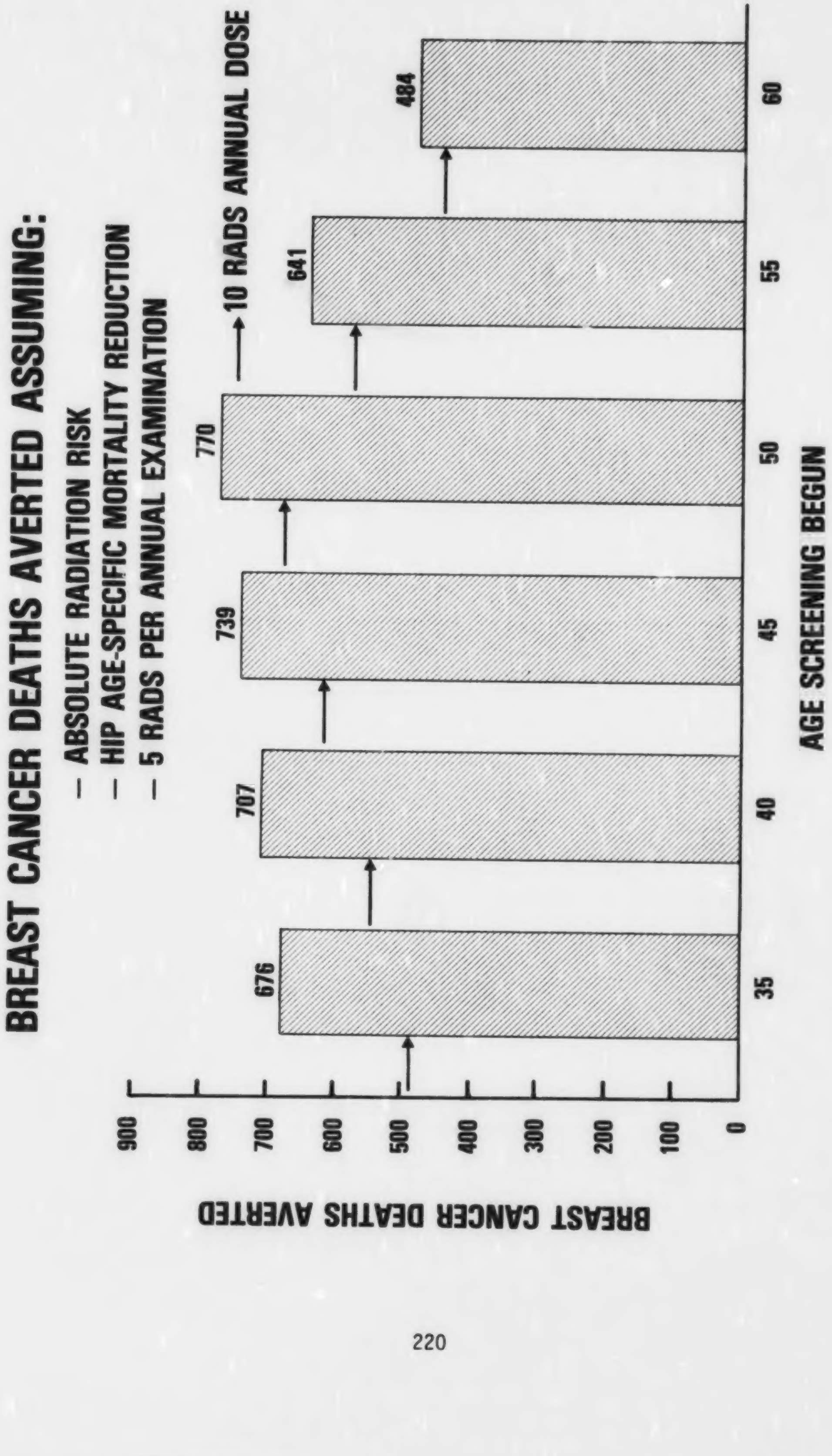
BREAST CANCER DEATHS AVERTED ASSUMING:
— ABSOLUTE RADIATION RISK
— HIP AGE-SPECIFIC MORTALITY REDUCTION
— 5 RADS PER ANNUAL EXAMINATION
→ 10 RADS ANNUAL DOSE
BREAST CANCER DEATHS AVERTED
900
800
700
600
500
400
300
200
100
0
676
707
739
770
641
484
35
40
45
50
55
60
AGE SCREENING BEGUN

Figure 6.

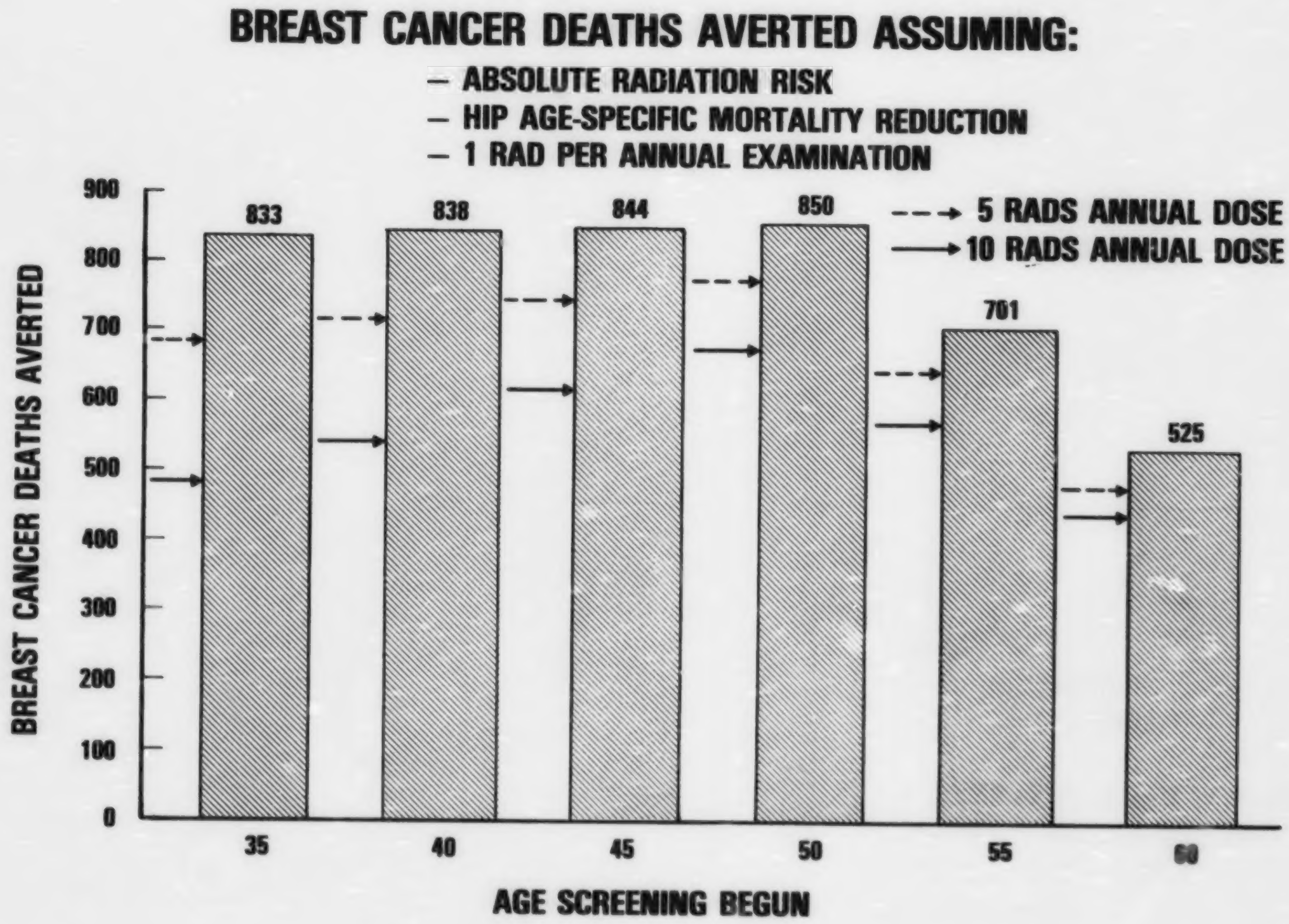
BREAST CANCER DEATHS AVERTED ASSUMING:
— ABSOLUTE RADIATION RISK
— HIP AGE-SPECIFIC MORTALITY REDUCTION
— 1 RAD PER ANNUAL EXAMINATION
- - → 5 RADS ANNUAL DOSE
——→ 10 RADS ANNUAL DOSE
BREAST CANCER DEATHS AVERTED
900
800
700
600
500
400
300
200
100
0
833
838
844
850
701
525
35
40
45
50
55
60
AGE SCREENING BEGUN

Figure 7.

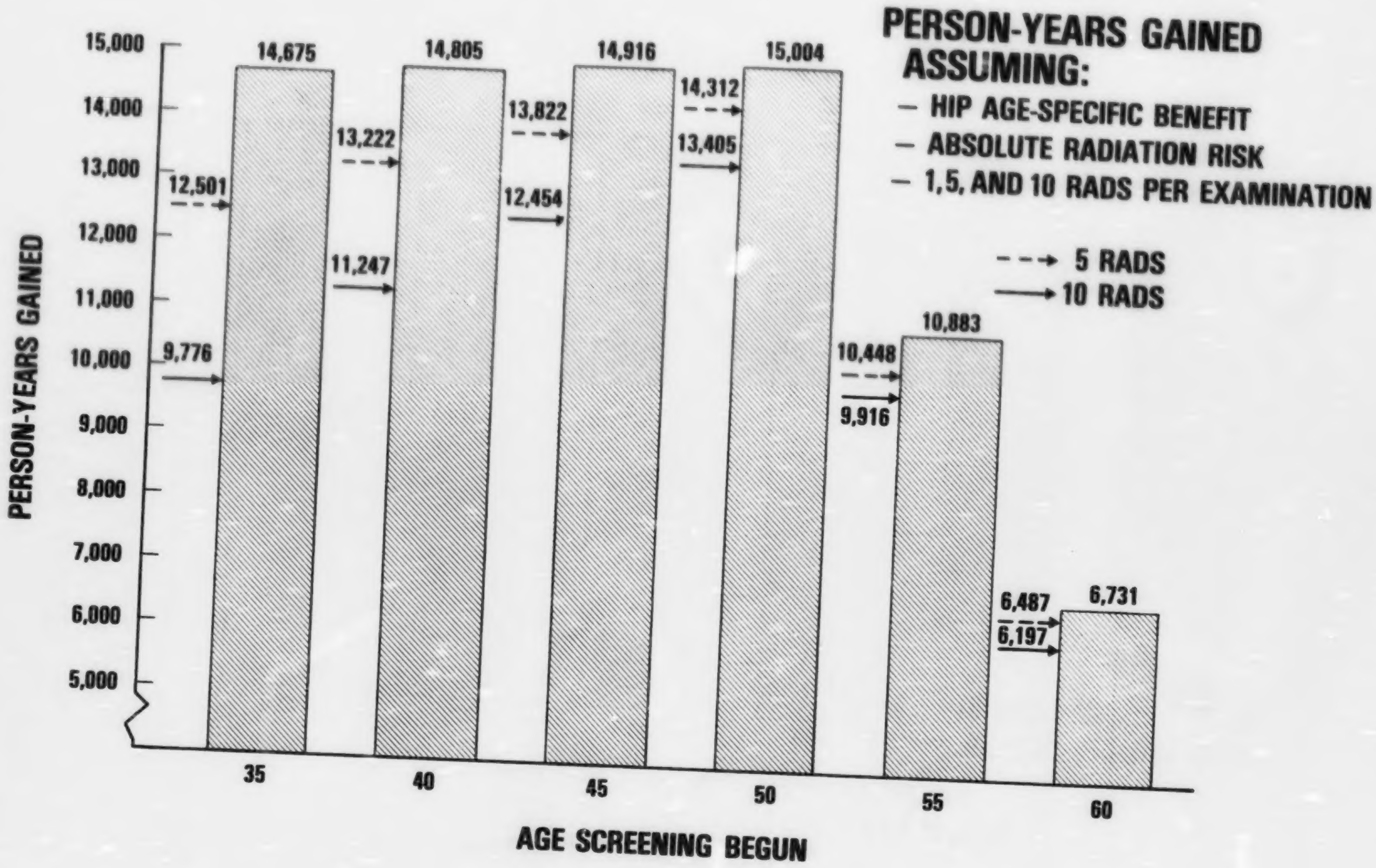
PERSON-YEARS GAINED ASSUMING:
– HIP AGE-SPECIFIC BENEFIT
– ABSOLUTE RADIATION RISK
– 1,5, AND 10 RADS PER EXAMINATION
- - → 5 RADS
——→ 10 RADS
PERSON-YEARS GAINED
15,000
14,000
13,000
12,000
11,000
10,000
9,000
8,000
7,000
6,000
5,000
14,675
12,501
9,776
14,805
13,222
11,247
14,916
13,822
12,454
15,004
14,312
13,405
10,883
10,448
9,916
6,731
6,487
6,197
35
40
45
50
55
60
AGE SCREENING BEGUN

Figure 8.

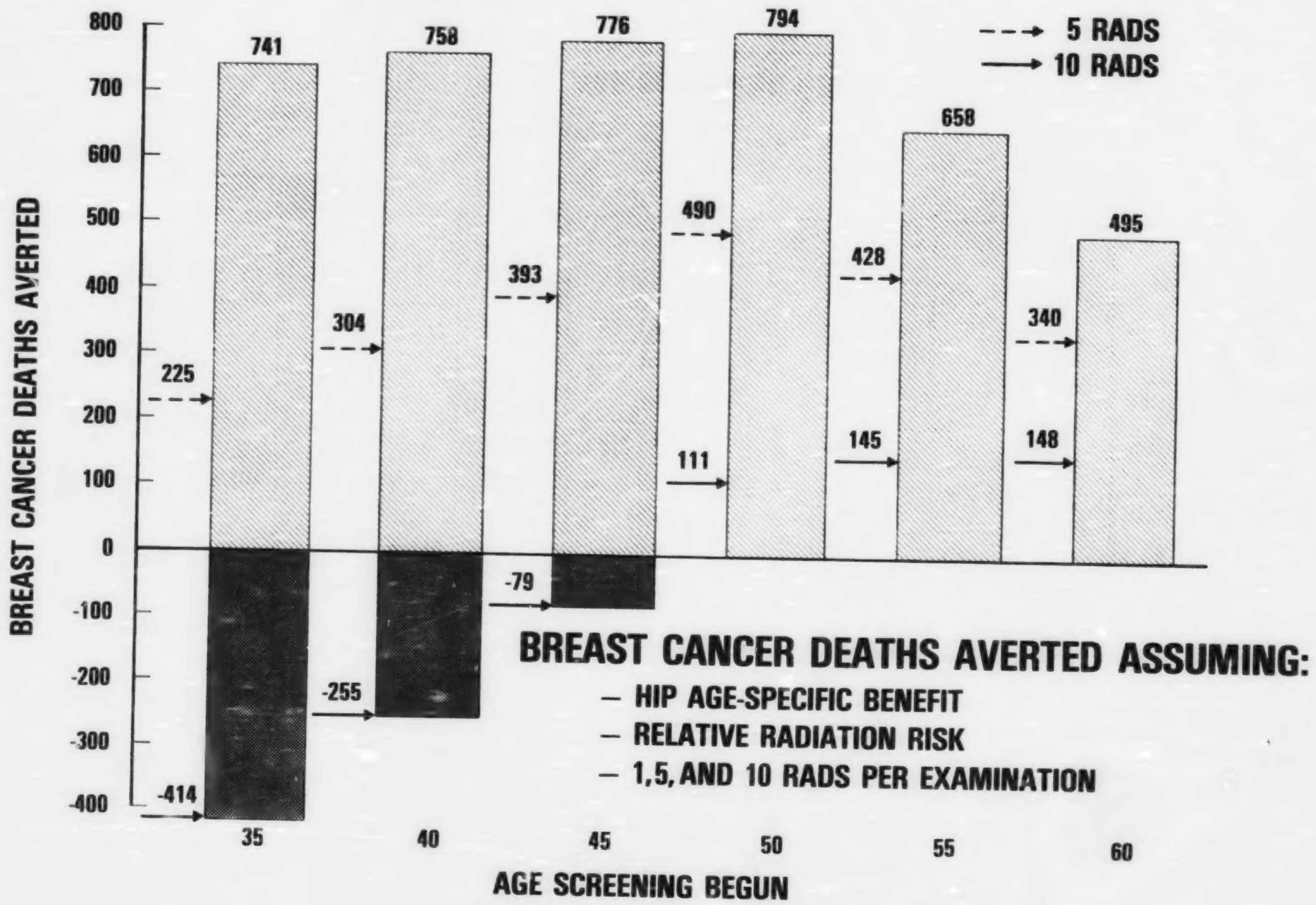
BREAST CANCER DEATHS AVERTED
800
700
600
500
400
300
200
100
0
-100
-200
-300
-400
741
758
776
794
658
495
225
304
393
490
428
340
111
145
148
-414
-255
-79
5 RADS
10 RADS
BREAST CANCER DEATHS AVERTED ASSUMING:
— HIP AGE-SPECIFIC BENEFIT
— RELATIVE RADIATION RISK
— 1,5, AND 10 RADS PER EXAMINATION
35
40
45
50
55
60
AGE SCREENING BEGUN

Figure 9.

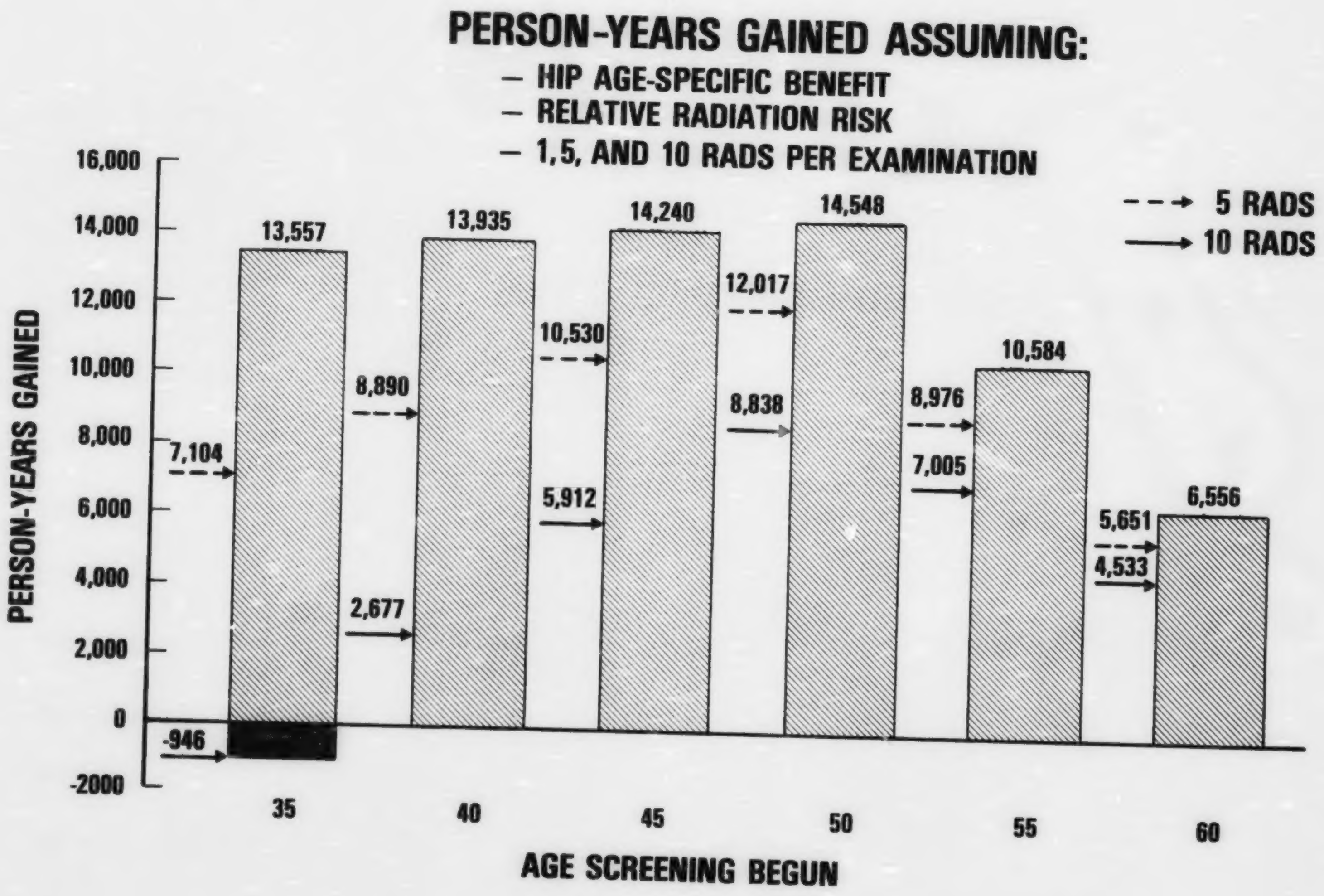
PERSON-YEARS GAINED ASSUMING:
— HIP AGE-SPECIFIC BENEFIT
— RELATIVE RADIATION RISK
— 1,5, AND 10 RADS PER EXAMINATION
5 RADS
10 RADS
PERSON-YEARS GAINED
16,000
14,000
12,000
10,000
8,000
6,000
4,000
2,000
0
-2000
13,557
7,104
-946
13,935
8,890
2,677
14,240
10,530
5,912
14,548
12,017
8,838
10,584
8,976
7,005
6,556
5,651
4,533
35
40
45
50
55
60
AGE SCREENING BEGUN

Figure 10.

Discussion

The analysis given here is based on numerous assumptions for both risk and benefit estimation. Though a complete discussion of the effects of these assumptions is beyond the scope of this report, the general direction of the attendant bias is indicated.

The assumed risk models may or may not overestimate the breast cancer induction rates from radiation. The procedures used to arrive at these estimates, however, are the same as those assumed to be conservative; i.e., to overestimate risk, by radiation protection groups for many decades *(8)*.

The assumptions made concerning the benefit are derived from the HIP study *(7, and a personal communication in 1975)* and are intended to err in the direction of a greater estimated benefit than would be expected in a general population. It is recognized, however, that the x-ray techniques used in the HIP study may have been less sensitive to tumor detection than current methods that may increase the life saving potential of screening and lower the age at which annual screening should begin.

The problems involving age at first screening are being considered in analyses which are currently underway using data from the most recent screening programs. The issue of screening frequency has not been considered in the present model because no studies exist which demonstrate the benefits of other than annual screening.

An observation made in this analysis which is not sensitive to the assumptions is the dose relationship. The contrast among the three doses shown of either deaths averted or person-years gained indicates that the lower the dose, the higher the benefits regardless of the age at which annual screening was begun. Thus, we believe that the desirability of dose reduction without a sacrifice of image quality has been demonstrated.

ACKNOWLEDGEMENT

Our deep appreciation is extended to Mr. Sam Shapiro for sharing with us the most recent unpublished data from the HIP study.

APPENDIX I

The equations and variable which constitute the life table model presented here are deterministic in nature and are based on the following notation. Let

x_i = exact age of the population at the beginning of the ith interval.

l_i = number of women alive at the beginning of the ith interval.

q_i = proportion of women alive at the beginning of the ith interval who die in that interval from all causes.

d_i = the number of women alive at the beginning of the ith interval who die from all causes.

M_i = the age specific mortality rate from all causes corresponding to the ith interval.

$M_{i\delta}$ = the age specific mortality rate from cause R_δ (in this instance breast cancer) corresponding to interval i.

L_i = the number of person-years lived in interval i by women who were alive at the beginning of the interval.

a_i = the fraction of interval i lived by women who died in that interval.

n_i = the number of years spanning the ith interval.

$Q_{i\delta}$ = proportion of women alive at the beginning of the ith interval who die from breast cancer in that interval.

$d_{i\delta}$ = number of women alive at the beginning of the ith interval who would naturally die of breast cancer in the interval in the absence of a screening benefit.

R_{ik} = increased risk per rad in the ith interval under risk model k.

$M'_{i\delta}$ = age specific mortality rate due to radiogenic breast cancer corresponding to interval i.

$I_{i\delta}$ = age specific incidence rate of breast cancer corresponding to interval i.

D_i^{EFF} = the dose in rads which is effective in interval i for induction of breast cancer.

$Q'_{i\delta}$ = proportion of women alive at the beginning of the ith interval who die of radiogenic breast cancer.

$d'_{i\delta}$ = number of women alive at the beginning of the ith interval who die of radiogenic breast cancer.

$d^*_{i\delta}$ = total number of deaths from breast cancer occurring in spite of screening in interval i.

$F^*_{i\delta}$ = the ratio of the HIP study to control mortality rates in the ith interval.

$s_{i\delta}$ = number of deaths from breast cancer prevented by the screening procedure in the interval.

$P_{i\delta}$ = person-years of life lost by women who died from breast cancer in the interval.

q^*_i = derived proportion of those entering the ith interval adjusted for deaths caused by radiation and lives saved by screening.

z_i = expectation of years of life lost by women who die in the interval.

The life table equations utilized here are essentially those given by Chiang (1968) with some modifications. Beginning with l_i, the computation of the number dying in the interval is given by

$$d_i = l_i \, q_i \tag{1}$$

To obtain an estimate of the subset of d_i who died from breast cancer, we utilize a formulation given by Chiang (9) for the probability of death from specific causes

$$Q_{i\delta} = \frac{n_i \, M_{i\delta}}{1 + (1-a_i) \, n_i \, M_i} \tag{2}$$

where $n_i = x_{i+1} - x_i$ (3)

and $a_i = \dfrac{L_i - n_i \, l_{i+1}}{n_i d_i}$. (4)

The L_i, l_{i+1} and d_i are taken from the U.S. Life Tables for 1973. The number of deaths from the specific cause is given by

$$d_{i\delta} = l_i Q_{i\delta} \tag{5}$$

The risk data is then utilized to form the mortality rate in the ith interval from radiogenic breast cancer. For the absolute risk model we get

$$M'_{i\delta} = \frac{D_i^{Eff} \, R_{11} \, M_{i\delta}}{I_{i\delta}} \tag{6}$$

where for purposes of this paper

$$R_{11} = 6 \text{ cases}/10^6 \text{ women/rad/year.}$$

For the relative risk model we get

$$M'_{i\delta} = D_i^{Eff} \, R_{12} \, M_{i\delta} \tag{7}$$

where

$$R_{12} = 0.008/\text{rad.}$$

Equation (7) assumes that a proportionate increase in the incidence will be accompanied by an equal proportionate increase in the mortality within each age interval. The probability of death from radiogenic breast cancer and the number of deaths are computed from $M'_{i\delta}$ by

$$Q'_{i\delta} = \frac{n_i M'_{i\delta}}{1 + (1-a_i) n_i M_i} \tag{8}$$

and

$$d'_{i\delta} = l_i Q'_{i\delta} \tag{9}$$

The number of breast cancer deaths which remain in spite of the screening procedure is computed by

$$d^*_{i\delta} = (d_{i\delta} + d'_{i\delta}) F^*_{i\delta} \tag{10}$$

The gross number of lives saved then is given by

$$s_{i\delta} = (d_{i\delta} + d'_{i\delta}) - d^*_{i\delta} \tag{11}$$

and the adjusted probability of death accounting for deaths caused and lives saved is calculated as

$$q^*_i = \frac{d_i + d'_{i\delta} - s_{i\delta}}{l_i} \tag{12}$$

The number of women surviving to the next interval is obtained by

$$l_{i+1} = l_i(1-q^*_i) \tag{13}$$

Finally, the person-years of life lost in interval i by women who died from breast cancer in that interval is given by

$$P_{i\delta} = d^*_{i\delta} z_i. \tag{14}$$

The l_{i+1} then becomes the new l_i and is fed back into the process beginning with equation (1). The process is repeated until the final age interval computations have been completed. It is assumed that the last age interval for women 85 years of age and over is 15 years long implying that all women have died by age 100.

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THE OPTIONS:
EQUIPMENT AND IMAGING CONSIDERATIONS FOR MAMMOGRAPHIC PROCEDURES

Robert Jacobs
Division of Electronic Products
Bureau of Radiological Health, FDA

Mammography is currently a widely used and accepted diagnostic examination for breast cancer detection. Several mammographic techniques are used by various practitioners. The range of radiation exposures associated with the proper conduct with each of these techniques has been reported to be from less than 1 to over 10 roentgens per view at the surface of the breast, with two or three views of each breast comprising a typical examination. This variability in technique is due to a variety of factors, some of which relate to the equipment used, and others which relate to the specific diagnostic information of interest.

At present, a large part of the female population of all ages is likely to undergo one or more mammographic examinations, and thus be subject to a significant exposure to ionizing radiation. It is well known that the exposure of the breasts to moderate or high levels of ionizing radiation results in increased incidence of breast cancer among the exposed individuals years after the exposure took place, and that this risk appears to be age dependent; decreasing with increasing age at exposure.

The Bureau of Radiological Health is actively participating in and supporting programs to develop methods to minimize the radiation exposure associated with mammography while still retaining the desired diagnostic information. Currently, a variety of x-ray tubes, technique factors, and image receptors are being employed in mammographic examinations. The exposure is strongly dependent on each of these factors. No consensus opinion of investigators in the field exists on the optimal technique or equipment. It appears that the choice depends upon the experience and preference of the practitioner and upon what features he deems most important to visualize. For example, xeroradiography is claimed to be superior in visualizing ductile patterns, whereas diffuse masses may be more easily detectable using film as the image receptor.

The task of estimating diagnostic efficacy of these various systems form physical measurements of their imaging performance is made almost impossible by the lack of information and diagnostic significance of the various radiographic manifestations of mammary cancer; that is, calcifications, tumor bodies, and perhaps others.

While it is obvious that it would be desirable to use an imaging system which could see everything, it may well be true that a system that could see only some things with a very low associated mammary dose could, because of risk/benefit considerations, be of value as a screening system. It is necessary to know the combinations of diagnostic signals which have been associated with confirmed positive diagnoses of mammary cancer of various types and stages so the relative importance of the various aspects of imaging performance can be studied.

The relative usefulness of tungsten or molybdenum anode tubes depends upon the thickness and composition of the breast. Determining the best tubes in terms of image quality and patient exposure is complicated by factors such as the x-ray energy spectrum emitted, attenuation properties of structures within the breast, scatter, and the energy response of the recording system.

The proportion of low energy radiation present in a spectrum is reduced as the thickness of filtration is increased. For very light filtration (such as inherent filtration of beryllium window tube approximately 0.05 mm Al) much of the exposure from a tungsten target is due to characteristic L x rays and thus a higher output is obtained compared with that from the molybdenum target for generator tor ges up to at least 90 kVcp. However, as the voltage is increased, the efficiency of production of molybdenum characteristic K x rays increases relative to that fro tungsten L x rays so that the relative output from the molybdenum target increases. Filtration by 0.5 mm of aluminum almost completely removes the tungsten L x rays so that the output from molybdenum is then greater than that from tungsten at all voltages above 30 kVcp. Further increase in filter thickness above 1.0 mm of aluminum considerably reduces the intensity of molydbenum K x rays so that the relative output from the tungsten target increases due to the greater efficiency of bremsstrahlung production for higher atomic materials (Z = 42 for Mo; Z = 74 for W).

The K absorption edge of molydbenum lies at 20 keV. Therefore, a molybdenum filter that produces the same attenuation as a given aluminum filter for x rays with energies less than 20 keV will have considerably greater absorption than the aluminum at higher energies. The molybdenum target, molybdenum filter combination should result in increased contrast, and therefore has some adlvantages over either molybdenum or tungsten targets with aluminum filtration when tissues up to approximately 5 cm are to be radiographed. The spectrum from a molybdenum target can only be changed significantly by use of different filter materials. The output above 20 keV through an aluminum filter is relatively greater than that through a molybdenum filter. The molybdenum target-aluminum filter combination can be used for thicker specimens where the penetration of the molybdenum K x rays is not sufficient. No further increase in hardness can effectively be obtained from a molybdenum target. Therefore for even thicker specimens a tungsten target would be required.

Recent work by Haus, et al. from the University of Chicago, studied the general relative effects of x-ray beam quality on image contrast in film mammography. The effect of breast tissue on the transmitted primary x-ray spectrum, rum, ence on radiographic contrast, depends upon the amount of fat relative to fibrous and glandular tissue present. Breasts composed primarily of fat yield images of higher radiographic contrast when imaged with the molybdenum rather than the tungsten anode tube at the same kVp, although the patient exposure required with molybdenum increases relatively faster with breast thickness. When the breast is very thick or contains a large percentage of fibrous and glandular tissue, the contrast obtained with a molybdenum anode tube will be similar to that obtained with a tungsten anode tube and the patient exposure will be greater.

Results by Evans, et al. in Glasgow have shown that it is possible with xeroradiography--in contrast to film--to produce images of equal quality using either tungsten target aluminum filter or molybdenum target molybdenum filter x-ray sources. The exposure is significantly reduced using the tungsten source. Their results show an average 50 percent exposure reduction. A molybdenum tube with aluminum filtration can be used for xeroradiography, however, the exposure will still be less by using a tungsten tube.

The Bureau of Radiological Health presently is supporting a contract with the University of Lowell to determine those x-ray spectra which are optimum in terms of exposure/dose required to perform a given detection task under varying conditions of tissue composition, tumor size, breast thickness, and image receptor/energy response function. Preliminary results indicate that the optimum spectra for tumor visualization are harder than generally employed in mammography. Another significant conclusion is that with an optimized spectrum, the exposure required to detect a small tumor body (about 1 mm) in background of only random noise; that is, in a simple homogeneous phantom, is on the order of 1 mR or less. This may have some implication for the advantages of machine or otherwise enhanced reading of mammograms. Research in image enhancement techniques could lead to substantial reductions in radiation exposure from mammography.

In the present practice of mammography, the use of the film-screen combinations deliver the lowest average dose, xeroradiography somewhat higher, and direct film the highest. Present Bureau activities in quality assurance are designed to reduce the average dose delivered within each of these techniques by identifying those facilities where exposures appear to be high and making recommendations to correct or improve one or more aspects of the examination.

The Bureau also is planning to publish a report that would reference data on factors such as: choice of x-ray tube target material, type and thickness of x-ray filter, peak kilovoltage, source-to-skin distance, image receptor, image qualities, and expected range of exposure to the patient Such a report could serve as a guide to the selection of the technique - equipment combinations appropriate for minimizing patient dose while obtaining the desired information.

Purely from a consideration of radiation dose, the use of a fast film-screen combination is now the obvious method of choice; however, the possible advantages of image quality of direct film, or the detection of microcalcification by xeroradiography, cannot be ignored. The choice now is that of the clinician and the information he deems necessary to make a meaningful diagnosis.

THE OPTIONS: MAMMOGRAPHY QUALITY ASSURANCE PROGRAM

Ronald G. Jans
Division of Training and Medical Applications
Bureau of Radiological Health, FDA

The Bureau of Radiological Health, FDA, is developing a Mammography Quality Assurance Program as a technique that can be used by radiation control agencies to minimize patient exposure from mammography and to improve image quality. I would like to describe the program to you and present the results to date from the pilot tests that are being conducted in cooperation with the Pennsylvania Bureau of Radiological Health and the District of Columbia Bureau of Occupational and Institutional Hygiene and Radiological Health.

The need for a Mammography Quality Assurance Program became evident with the wide range of reported exposures from the various mammographic techniques. One year ago, at the Seventh Annual Conference in Hyannis, Hank Bicehouse presented the results of his study on mammographic exposure levels and techniques in Eastern Pennsylvania.

In Pennsylvania, Bicehouse surveyed 70 medical facilities during routine State compliance inspections. These included 45 hospitals, 23 radiologists' private offices, and 2 clinics.

Using LED's (low-energy dosimeters), Bicehouse measured the exposure from a single craniocaudal view of a "medium-density, medium-sized" breast. He found that the mean exposure by type of image receptor ranged from 1 to 24 R and that individual exposures were as high as 47 R.

Five facilities were overexposing and underdeveloping their film, resulting in a mean exposure per film of 39 R. This group included the 47 R exposure.

The mean exposures for xeroradiographic, film/screen, and non-screen medical and industrial film techniques using 500 mAs or less ranged from 1 to 3 R per film. Finally, the "high density" techniques using industrial film and more than 500 mAs resulted in a mean exposure per film of 24 R.

In addition to these findings, Bicehouse observed that:

(1) 1/3 of the facilities did not follow the recommended development procedure of the film supplies. Included in this group are facilities that rapid-processed industrial film that should have been hand processed.

(2) 2/3 of the facilities had total filtrations of 1 to 2.5 mm, of aluminum, which seemed to indicate a lack of optimization of the x-ray energies being used for mammography.

In summary, Bicehouse concluded that approximately 3/5 of the surveyed facilities had not optimized their mammographic procedures for x-ray energies and image receptor development.

Two problems are evident from Bicehouse's work:

(1) In many cases, exposure per film is unnecessarily high; and

(2) Even if the exposure appears acceptable, the image quality may not be optimal.

The second problem requires a major effort on the part of all health professionals. There still exists considerable debate regarding which energy spectrum is the best for a given image receptor and even which image receptor is best for mammography.

In the Mammography Quality Assurance Program, we are attempting to correct the first problem, unnecessarily high exposures, by using an approach similar to that of the DENT program. At the same time, we are collecting much needed information on the current practice of mammography.

As many of you are aware, the DENT program utilizes thermoluminescent dosimeters to identify facilities where the exposure per film exceeds an acceptable range. Identified facilities are then visited by trained personnel and corrective actions are recommended.

Although we recognize that mammography is more complicated than dental radiography because of difficulties in soft-tissue visualization and the large variety of image receptors and x-ray generating equipment, we believe that with proper controls an approach similar to DENT will be productive when applied to mammography. The pilot tests of this program in Pennsylvania and the District of Columbia should demonstrate that facilities with unnecessarily high exposures can be identified and that corrective action can then be taken.

The Mammography Quality Assurance Program operates in four phases. These four phases are: groundwork, screening, followup surveys, and evaluation.

During the first phase--groundwork--it is necessary to contact and obtain the support of the ACR, local radiological societies, and local medical societies. A good relationship with these groups is critical to the success of the program. Both pilot tests have proceeded with their support and the rapid turnaround of survey materials and the high response rates in the pilot tests are a result of their cooperation.

After obtaining the support of the various professional groups, physicians are mailed a survey card to identify the facilities conducting mammographic examinations. Those facilities responding "yes" are asked to identify the number of patients receiving mammograms and the percent of those patients under 50 years of age. They are also asked to indicate whether or not they routinely screen asymptomatic patients with mammography.

During the screening phase, facilities will be mailed thermoluminescent dosimeters for each mammographic unit. They will expose the card at the technique factors that would normally be used for a craniocaudal view of a "medium-density, medium-sized" breast, complete the information requested on the back of the card, and return it for analysis.

Each exposure will be grouped with exposures from other facilities using similar image receptors in order to identify those that are unnecessarily high.

The TLD's are packaged in a 3-½" by 5" card, that can be mailed without damaging the TLD's. A foldable cardboard support is used to position the TLD's at the skin entrance site for an "average" breast. A 1-millimeter thick, aluminum disc under the TLD's prevents variations in backscatter.

On the reverse of the card, the technologist records the technique factors, type of image receptor, type of film processing, and the type of views in an average mammographic study.

Each of the facilities completing Phase II will receive a report on the exposure at his facility in relation to the distribution of exposures for the various image receptors. Facilities whose exposures appear unnecessarily high enter Phase III of the program.

During Phase III, office visits will be scheduled for the identified facilities. Trained individuals will perform a variety of measurements involving the x-ray unit and the image processing system. At the end of the visit, they will make recommendations to improve one or more aspects of the mammographic technique, if needed. The pilot tests in the District of Columbia and Pennsylvania are being used to develop the protocols for these visits.

During Phase IV--evaluation--the effect of recommendations made during the followup surveys will be assessed by a subsequent mailing of TLD's several months later.

As I mentioned earlier, this program is currently being pilot tested in Pennsylvania and the District of Columbia.

Pennsylvania began their pilot test by arranging to have an article on the program published in the Pennsylvania Radiological Society Newsletter. Following the publication they mailed 1250 survey cards to osteopaths, M.D.'s, hospitals, and clinics with registered x-ray equipment.

Overall, nearly 80 percent of the cards were returned. The return rate for hospitals and clinics was over 95 percent. Of the facilities that returned cards, 238 (or 24 percent) indicated that they were doing mammography. The majority of these facilities were using only one x-ray unit for mammography.

The facilities doing mammography indicated that they examined 9400 women in 1 month during 1975. (That month would have been either November or December.) These same facilities examined 9700 women during the same month in 1974. It was during this period in 1974, as you may recall, that the press was carrying accounts of breast cancer being found in Betty Ford and Happy Rockefeller.

Forty-five percent of the women examined were under 50 years of age.

Most of the facilities were examining 40 or fewer women per month. Thirty-nine facilities examined from 40 to 100, and 21 facilities examined 100 or more per month (see Table 1).

Table 1. Workload of mammography facilities in Pennsylvania

PA PILOT TEST

# OF FACILITIES	# OF WOMEN EXAMINED IN ONE MONTH
176	40 OR LESS
39	MORE THAN 40 LESS THAN 100
21	100 OR MORE

The 21 facilities examining 100 or more women per month accounted for 53 percent of the total examinations. The other two groups of facilities accounted for 25 and 22 percent of the examinations, respectively.

In the District of Columbia, 18 facilities are participating in the study. These facilities were identifed by a telephone survey and then mailed dosimetry cards. Because there are only 18 facilities in the D.C. pilot test, each is receiving a followup visit. The purpose of the visits is to evaluate the accuracy of the TLD's, to develop a survey protocol that can be used in Pennsylvania, and to obtain patient data similar to that from Pennsylvania.

In order to be able to compare the exposure from a given facility in D.C. and Pennsylvania to exposures from facilities using similar techniques, we have categorized the techniques as film alone, film/screen combinations, and xeroradiography.

The film alone category includes direct exposure industrial films such as Kodak AA and DuPont 55-75 and direct exposure medical films such as Kodak RP/M, Duo Pac, and SO 146.

The most common types of film/screen combinations were DuPont Lo-Dose and Kodak X-Omatic G film with Industrex screens.

In the District, two facilities are using film alone, six are using film/screen combinations, and ten are using xeroradiography.

In Pennsylvania, 46 percent of the facilities are using film/screen combinations. Note that while only 24 percent of the facilities used xeroradiography, they examined 40 percent of the women (see Table 2).

Table 2. Percent of women examined in one month by type of image receptor in Pennsylvania

PA PILOT TEST

% OF FACILITIES	IMAGE RECEPTOR	% OF WOMEN EXAMINED IN ONE MONTH
30	FILM ALONE	15
46	FILM/SCREEN COMBINATION	45
24	XERORADIOGRAPHY	40

The next three figures show the distributions of exposures for each of the three categories of image receptor. In figure 1, exposure in roentgens from a craniocaudal view is shown on the x-axis. This exposure is essentially equivalent to exposure free-in-air at the skin entrance site. The y-axis is frequency, or the number of x-ray units with a given exposure.

Exposure for the 58 x-ray units used with film alone techniques ranged from 300 mR to 17 R (see Fig. 1). The mean exposure was 3.2 R and the median exposure was 1.9 R. Three out of the 58 units were used with industrial film. The remaining 55 units were used with direct medical film.

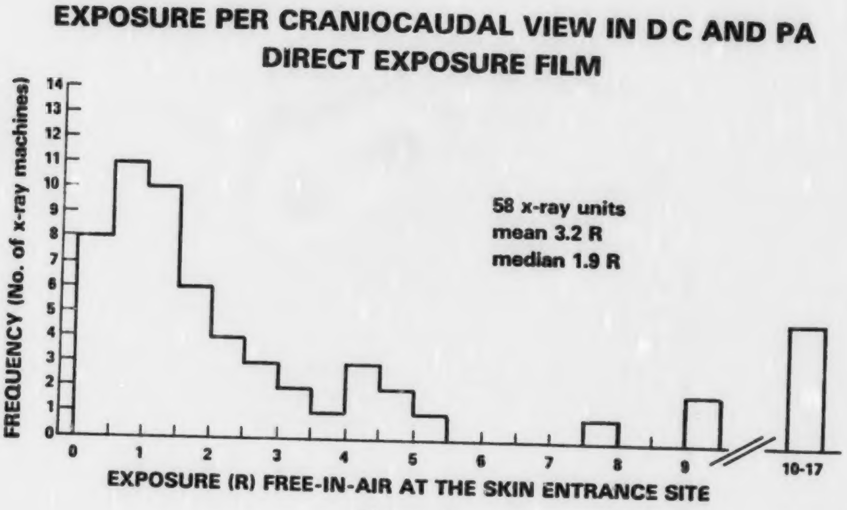


Figure 1.

Except for the 17 R exposure, the 8 exposures over 8 R were from special purpose mammographic units and medical film at 600 mAs or less. The 17 R exposure was from a Senographe being used with industrial film.

Ninety-seven x-ray units used film/screen combinations (see Fig. 2). DuPont Lo-Dose and Kodak X-Omatic G with Industrex screens were the most common types. Both the mean and median exposures were less than 1 R. Seven units had an exposure of 2 R and above.

The last category is xeroradiography (see Fig. 3). The range of exposures for the 65 x-ray units used with this technique was from 250 mR to 7 R. The mean and median exposures were less than 2 R. Nine facilities had an exposure of 4 to 7 R. The workload weighted mean craniocaudal exposure for all technique was 2.1 R.

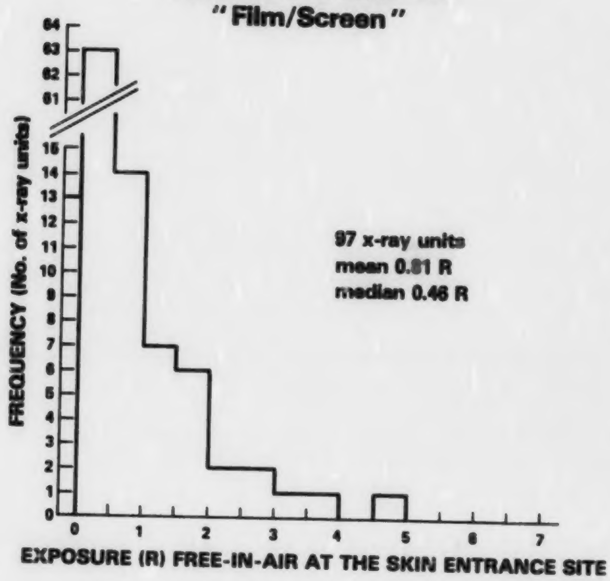
The data gathered on types of image receptors and exposure are being used to select facilities for followup visits.

In the District, each facility is receiving a followup visit in order to confirm our dosimetry. With over half of these visits completed, it appears that TLD's are sufficiently accurate as a screening tool for high exposures. The followup visits in the District also had the unexpected benefit of discovering two facilities where, even though the exposure was less than 2 R per film the Lo-Dose film was being incorrectly loaded into the vacuum cassette. Correction of this problem will result in better image quality with less exposure.

Two other facilities have indicated that they would modify their procedures based upon the survey, resulting in a reduction in exposure at each facility.

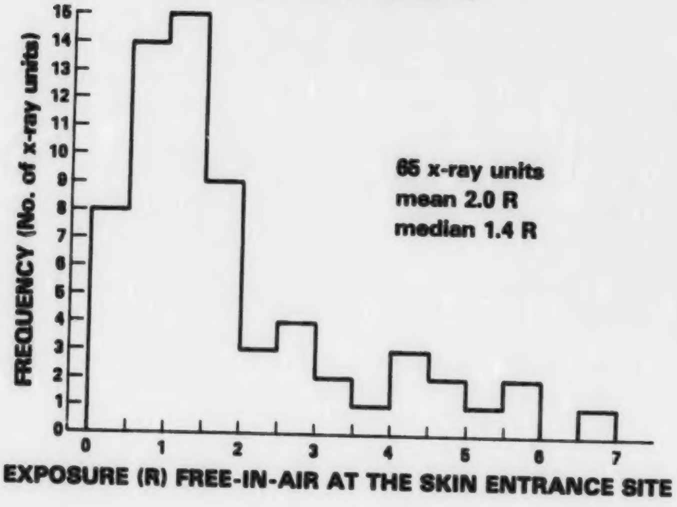
The followup visits in Pennsylvania will be starting in the next few weeks. Facilities are being identified by several criteria, such as:

1. The exposure appears too high.
2. The exposure appears too low. (Some examples; one facility reported that they used 3 mAs for a craniocaudal view with Lo-Dose film. The exposure on the dosimetry card was 4 mR. Another facility reported



EXPOSURE PER CRANIOCAUDAL VIEW IN DC AND PA
"Film/Screen"

Figure 2.



EXPOSURE PER CRANIOCAUDAL VIEW IN DC AND PA
Xeroradiography

Figure 3.

technique factors which should have resulted in a exposure of 5 to 10 R, yet only 800 mR was recorded on the dosimetry card.)

3. Reported image receptors and image processing appear to be less than optimal. (There were seven reports of film other than mammography film being used. Followup of these situations will determine whether or not these were mistakes in responding to the questionnaire. Corrective action can then be recommended.)

The data which have been collected and the cooperation we have received from radiologists lead us to believe that this program will be successful.

The completion of the pilot tests in the next few months will enable us to evaluate the accuracy of the data and to determine whether or not it will be possible to recommend corrective actions which will result in lower exposure and improved image quality.

If the program is indeed successful, we plan to train the Regional Radiological Health Representatives in the program during the fall. The program will then be available through them.

THE OPTIONS: NYC MAMMOGRAPHY REGULATIONS

Leonard Solon, Ph.D.
Director, Bureau of Radiation Control
New York City Department of Health

The widespread media exposure given to breast malignancy as a result of the involvement of two well known public figures has underscored the fact that cancer of the breast is presently the leading cause of death from cancer in women(1,2). As a result, there has been an important increase in the number of mammographic examinations at facilities offering such examinations within the City of New York. We estimate that about 200 offices and clinics are performing such examinations.

As a result of its regular x-ray inspection program, it became apparent to the City Health Department s Bureau of Radiation Control that a significant number of such installations were departing from good radiation hygiene practice. Probably the greatest single source of superfluous radiation exposure in mammography is the use of less costly slow film as the image receptor, instead of the low dose film designed specifically for mammographic applications(3,4,5).

Another important source of excessive radiation exposure is permitting the useful beam to encompass materially more than the breast. It is a sine qui non of good radiological health that the x-ray beam be confined to the area of clinical interest. Also the use of mammography as a mass screening mechanism in completely asymptomatic women under the age of 35 or 40 is counter to good public health policy, because of the associated radiation risks(6,7). A case has been advanced by some experts in breast malignancy epidemiology that indiscriminate mammographic screening will actually result in an increase in breast cancer as the result of population radiation overexposures(6,8).

On September 18, 1975, the Board of Health of the City of New York, following a staff study and recommendation of the Bureau for Radiation Control, pioneered in adopting a regulation addressing itself to the aforementioned problem areas. This regulation may be found appended to this paper.

One of the provisions of the regulation provides for the practitioner to elicite from each new patient reports of prior mammographic examinations in the previous 2 years. We suspect that a certain number of asymptomatic women are seeking the constant psychological reassurance of being free of breast malignancy by having frequent and unnecessary mammograms taken by different clinicians every few months. Needless to say, such a practice carries with it a greatly elevated risk of radiation-induced injury, including breast cancer.

Mammographic technology is very much in a state of evolution. Even with the advances made to date, one can safely characterize the present state (1976) as early. There are several different techniques in use, and it is probable that each of these is important in the diagnosis of various forms of breast malignancy. The present methods include techniques in mammographic radiology, of which xeroradiography is one. In addition, there are newer methods involving thermography and ultrasonics.

Breast cancer is the leading cause of cancer death in American women and is the chief cause of all deaths in women 40 to 44 years of age. Over 30,000 women die annually, and over twice that many new cases occur annually. There has been no demonstrable increase in the survival rate from breast cancer since 1930;

however, a 10-year survival of patients without metastases in the axillary lymph nodes is 70 percent to 90 percent(1,2).

More than 90 percent of malignant tumors are detected by the patient herself as the result of inadverence or selfpalpation. Unfortunately, by this time these tumors are usually 3.0 cm to 3.5 cm in diameter. At this phase, axillary matastases are to be found in about 65 percent of the patients. Half of these patients do not survive more than 5 years after surgical interventions. The fundamental advantage of mammography is that it can disclose some breast cancers 2 years before the clinical diagnosis. The 10-year survival rate for those with axillary matastases is only 24 percent(2,11,12). Mammography is 90 percent accurate when interpreted by skilled radiologists, while clinical diagnosis is only 70 percent reliable in expert hands. Quality mammography will reveal lesions as small as 5 mm and calcifications of 0.5 mm and smaller have been seen. The practical limit of visual resolution is of the order of 0.1 mm. A 1-cm-diameter benign fibroadenoma with its smooth margin and coarse dense calcification is not palpable clinically, but can be recognized at a glance on a good mammogram 14,15). A view held by some radiologists is that an important, perhaps the most important, reason for undertaking mammography is not so much to be able to describe the type of lesion visualized on a radiograph, as to be able to differentiate between benign and malignant tumors(16,17,7). However, as we have heard in part, mammography has its limitations. Among the disadvantages are that it is most effective as the amount of fat relative to other tissue in the breast increases, and hence, in general, is not especially advantageous for younger women where this ratio is low(8). The age for maximum effectiveness is almost certainly above 35 years, and perhaps is in the 50 s or 60 s, because of the radiation risks involved(6,19).

Secondly, approximately 12 percent of breast cancers cannot be disclosed by mammography under any circumstances at the present state of the art(20). Thirdly, the harmful effects of the radiation involved are certain, but difficult to quantitate. Indications are that if annual examinations are involved, it would be prudent from a public health sense that they be restricted to selected high-risk women, based on age, prior medical history, family experience, and other suggested factors such as complaints of pain in the breast and the cystic condition of the breast(7).

Fourth, there is a paucity of fully trained personnel. A proper diagnosis requires a high involvement of a physician specialist. One cannot help but wonder how many inadequate mammograms and faulty interpretations are being performed because of an insufficiency of medical experts.

Mass screening, so far, has involved relatively small groups of the female population. However, in the aggregate, the numbers--perhaps a few hundred thousand or so--are not inconsiderable. Since it takes many years, at least 5 to 10, and preferably 10 to 20, of followup studies to ascertain the ability to extend lifespan, it is difficult to speak with confidence of the advantages and disadvantages of mass screening. From a study involving 88,000 women, it has been calculated according to Dr. Benjamin F. Byrd of the American Cancer Society, that two and one-half times the number of breast cancers have been found in mass screening as compared to self-examination. Of the cancers discovered, 77 percent were still confined to the breast, and had not yet developed a metatastic spread through to the adjoining lymph nodes.

In another mass screening study, conducted by the New York City Health Insurance Plan (HIP) and involving two "random" samples each of 131,000 women aged 40 to 64. One group was offered screening by clinical examination and mammography, and the other served as a control population. The preliminary results show a lower mortality from breast cancer in the group offered screening, the respective rates being 2.2 deaths per 10,000 person-years, compared to 3.7 deaths per 10,000 person-years. The benefit appears to be almost restricted to the 50 to 59 year age group, and is not noticeable until 2 years after entry into the investigation(21). One hopes that selective mass screening could save lives, but the data to prove this conclusively is not available.

Employment of both a large sampling group and a rather lengthy followup time are required to secure meaningful survival data. Indeed, there are some adversaries to mass screening involving mammography, who have made a compelling case that the radiation risks involved in indiscriminate screening may be greater than the advantages(8). It is clear that with radiation dose lowered significantly by the use of low-dose film techniques(4), mass screening programs involving selected high-risk groups (again as opposed to indiscriminate screening), are more defensible. With procedures involving higher dose techniques, the sampling would have to be extremely conservative in choosing high-risk samples. Mass screening programs employing palpation, thermography, and perhaps ultrasonics with limited use of radiographic mammography may well be the future direction of diagnosis. To annually screen 38 million women in the United States who are 40 years of age and older, 1,900 centers, screening 100 patients per day would be required. At present, this would require 3,800 mammographic radiologists plus 26,000 technologists, secretaries, and supporting health personnel at a projected annual cost exceeding $620 million(10).

The techniques involved in mammography are extremely varied, as can be seen from mammographic equipment surveys conducted by New York City s Bureau for Radiation Control in cooperation with the New York State Department of Health. Survey forms were sent to 140 locations in New York City where a previous survey by public health sanitarians for the Bureau for Radiation Control indicated that mammography and radiography was performed. A review of the data disclosed widespread use of various x-ray equipment and tube types. Of the 81 replies, there were 22 different models of x-ray equipment. Fifty-eight of the 81 replies indicated the type of tubes used; 28 had molybdenum targets, 27 had tungsten targets, and 3 had molybdenum-tungsten targets. Thirty-one units were designed specifically for mammographic radiography, while the others were multipurpose. There was one Picker three-phase unit in the group. Six units used Xerox plates image receptors, 46 used Dupont low dose film/screen combinations, and 19 used nonscreen film. Without exception, the lowest mAs per exposure recorded was for molybdenum target tubes used in conjunction with low dose film/screen combinations.

The majority of radiologists are using low dose film/screen combinations. Although techniques varied, a general consensus among radiologists could be discerned. A craniocaudal and lateral plate for each breast should be done(22). Compression of the breast and coning are desirable, as they contribute significantly to the improved detail of the mammogram produced and the dose of radiation to the skin and to the patient(22,23). Mammography should be done with a special tube having these general specifications: a large diameter, heavy anode, a high heat capacity, ease of rotation, and air or water cooling; total filtration of about 0.5 mm Al for tungsten anode, or 0.3 mm molydbenum for a molybdenum anode; a relatively small target angle for high milliampere capacity and small focus; a maximum rating of 60 kVp (it should be observed that mammography is rarely performed over 40 kVp)(22); and relatively long target to skin distance should be used to reduce the skin dose and increase the definition(23). Ideally, the motions of the breast should be kept below 0.5 millimeter(13).

Mammography is always indicated for a patient with breast complaints(22,7). The fastest practical film exposed to the highest practical optical density should be used. Type M film is not recommended for routine use. If it is the only film available at a mammographic facility, it is a sure indication of inadequacy. In general, film technique choices can be categorized into five groupings. There are techniques employing industrial films with less than 500 milliampere-seconds exposure; techniques employing medical films, but no screen, also below 500 mAs; xeroradiographic techniques; "low-dose" techniques employ low mAs and screen; then, of course, the undesirable "high density" techniques, where the milliampere-seconds exceed 500(3).

Xeroradiography is the production of an image using a photoconductive surface, electrostatic charges, and x-ray xerographic type processing. Assertions of advantage for certain types of breast cancer, such as dense fibrocystic breasts have been made because of the "edge enhancement" effect. However, xeroradiography may not be as effective with other types of breast cancers, as silver halide film. Xeroradiography, as compared to traditional x-ray technique remains a matter of personal preference with strong supporters on either side. The doses and voltages involved appear to be somewhat higher than with x-ray film, but even this is arguable(24,5,25).

Thermography is a method of constructing photographic images of surface temperature. It registers the heat pattern of the breast detected by infrared sensitive instrumentation. Its chief advantage is that there is no hazardous radiation involved; however, thermography, because of its poor accuracy, cannot replace x-ray mammography at present. It may be able to supplement radiographic mammography, particularly in followup examinations(9,26,27,28).

Ultrasonics has been employed in breast mammography, but its use is still in an early stage. High accuracy has been claimed for certain types of breast cancer. Its chief advantage is that the levels of ultrasonic energy involved in such diagnosis have not been shown to cause any hazard to the patient(10,22).

Field reports on mammographic installations are reported by the inspection staff of the Radiation Equipment Division of the Bureau for Radiation Control. These surveys, begun in January 1976 as part of our regular program, are too few in number as yet for the extraction of meaningful general data.

There are some points of interest, however, that could be noted. First, the number of exposures at each installation were four for an average patient. In those installations where general purpose radiographic filtration was used for mammographic exposures, the exposure doses were exceptionally low. Since these units use nonscreen film, there is some question in our minds as to the diagnostic quality of the results. We find that there has been an increase in the total number of mammographic film exposures in some facilities, but a decrease in others since last year (i.e., 1975).

We also found that the radiologists did not always establish the operating technique. Sometimes the x-ray technician followed the instructions of the x-ray unit manufacturer, and in some cases, the x-ray technician established his or her own technique. Frankly, we find this automomy disturbing. The majority of those patients radiographed fall in the 36 to 65 year age category; however, nearly 10 percent fell below the age of 35, and mammography in this age bracket, if not accompanied by clinical symptoms or family history of breast cancer, is dubious at best(6,19).

The Director of the Federal Bureau of Radiological Health (BRH) has expressed the thought that more information on the effectiveness of the mammographic examination in detecting breast cancer is needed before screening programs can be endorsed. The BRH has initiated an indepth review of available data relating benefit and risk from the mammographic screening for cancer. The review will cover risk versus benefit of mammography as a function of age at the time of examination, alternative screening methods, techniques which provide satisfactory results with the lowest radiation dose, and desirable frequency of screening.

In addition, BRH is supporting research in optium radiographic techniques for mammography. This project is attempting to determine the radiation spectra which will produce the maximum yield of diagnostic information per unit of patient dose. This will be accomplished by studying radiation absorbing properties of mammary tissues and diagnostic indicators of breast cancer and radiation emission characteristics of x-ray tube target materials(29).

In our view, the BRH program has the right thrust and promises results of the greatest importance. We would hope to integrate the findings of the BRH investigations and our own field experience in New York City to achieve improvements in New York City s mammographic code.

However, initial experience with the pioneering code already has been favorable, with important improvements in mammographic practice as a result of implementation of the detailed provisions in the regulations. We are confident we are on the right public health track in terms of radiation control surveillance of mammographic installations in New York City. Not only does our regulation reduce superfluous radiation exposure, but it gives the marginal practitioner an incentive to reexamine his technique and strive toward mammograms of better diagnostic quality.

DISCUSSION

DR. MOSKOWITZ: I think it is very important that several points be emphasized. One point that we have to be very careful about is that we are not throwing away the baby with the bath water. We have all heard that there is some value to mammography and that there is not some value to mammography. We all agree that increasing the dose is bad, and because some people are practicing poor technique, it is our job to monitor technique and try to teach them a little bit about the process. This is what we should be doing and what we should be about.

However, to make sweeping categorical statements that mammography is of no value under age 50, and using only the HIP data as supporting evidence, shows the fallacy of taking an excellent and well-designed study, which has been poorly applied, and using the data from the study. If you do not find a significant number of curable cancers under age 50, you will not be able to find patients who have curable disease; ergo, you will have no benefit. Any study based upon those data is bound to show the same thing. If you look very carefully at the HIP data, by the strict definition we talked about, you may question how many of the curable cases exist in the under 50 age group. I have been unable to get the exact data from these people to be able to say how many of the cases were minimal cancers.

However, one thing that is apparent is that less than 20 percent of cancers found under the age group of 50 were found by mammography alone, which is entirely contrary to our experience. It is also contrary to the size and stage of cancers that have been found in younger women by an agressive approach. I am not saying that we have, at this point in time, all the answers either; we certainly do not. I think, though, that we have to sit down and look at this a bit more. We should allow ourselves the opportunity to realize that there may very well be a great deal more benefit in examining a woman who has no palpable lump, who may have disease in its earlier stages, rather than waiting until she has breast disease symptons. As far as I am concerned, when a woman presents me with breast disease symptoms, and I can diagnose the symptoms as cancer, it is already too late. That is an incurable disease; the disease is preordained and predestined no matter what we do with it, and that is unfortunate.

Unfortunately, another problem is that thermography is used as a prescreen, or as a potential screening tool. We have tried deliberately to avoid mention of thermography. I am not an antithermographer as much as Dr. Milford is, because you can always point a finger at us and say, "You have no experience in thermography;" fine. We have just finished a study, with the cooperation of 11 expert thermographers throughout the country--people whose names you would recognize. We have published the study in a paper that is going to be coming out in a journal, compared with a group of 9 naive readers. They were given 150 "unknown" thermograms to read. The patients thermograms were comprised of 67 patients selected from a random based screening population, 42 patients with minimal or in situ breast cancer proven, and 44 patients that had benign disease proven by biopsy. The true positive rate did not equal the false positive rate, if you gave them credit for calling both sides. If you gave them credit for calling only the wrong side, the false positive rate was double the true positive rate.

At this point in time, it does not seem as if a human eye can use thermography well, unfortunately. So we are stuck with the modality. We have an opportunity, I think to do something. I am not trying to say that we should be already screening every woman in the world; but used well and used intelligently, we have an opportunity right now to turn a condition around. When we have some other tool to take its place, we should throw it out. But, in the meantime, we should not be too agressive about what we throw away.

DR. ALCORN: I appreciate Dr. Brown mentioning the fact that the straight line extrapolation to zero dose is not necessarily true; a whole coterie of radiation biologists do not believe this. They feel that down below 50 R the degree of uncertainty is enormous. Since the publication of the BEIR report and the NCRP bulletin No. 43, there is another publication on low dose estimation by the National Academy of Sciences published in 1974, which raises serious questions as to the validity of this. You must remember that this is a matter of convenience and as you get down to very low doses fractionated out of a person s lifetime, one really does not know what is happening.

In addition, in a personal conversation with Douglas Grant within the last month, I found that they are going to bring out a new bulletin from the NCRP. For the low doses below 50 R, the net biologic effect should be divided by 5, so that we are going to have a break in the curve. I think that everyone in the audience should be aware that among outstanding radiation biologists in this country, this extrapolation from a high dose is held in considerable question. It was done primarily from single dose of high dose rates from the atom bomb explosions at Hiroshima and Nagasaki, and it provided a convenient mathematical way of estimating risks.

Lastly, for those of us that do mammography, there are very few asymptomatic persons, and they are all worried about something. As Dr. Moskowitz has told us, there is an enormous amount of self-selection among these ladies who present themselves to screening physicians for study.

DR. CHIACCHIERINI: There does not exist a proven, scientifically accurate dose/response curve. It is a prudent model to assume, by assuming a risk. The data which you refer to is known to me; the factor of 5 lowering of the risk; I have seen the basic information. I have not seen the true data, but I have seen the results of the paper presented by Dr. Upton. While I would agree that it gives us another estimate of risk, it certainly is not the most definitive estimate of risk, and probably will be as widely debated as the linear, non-threshold estimate of risk. So, I am not ready to jump on the bandwagon of the new estimate of risk, and totally abandon the old estimate of risk, when probably neither accurately describes the case. I think the same approach may be that we would look at each of them in their proper perspective, apply each of them in the model, and see what the results would do. However, to accept one at the exclusion of the other would be an injustice.

DR. SOLON: Two years ago, the radiological communities, so far as they have a spokesman, did in fact endorse and recommend that asymptomatic women, defined in a particular way (free of medical complaint, no strongly suggested family history of malignancy involvement) not be subjects of routine mammographic screening. To my knowledge, that position has never been rescinded by the American conferences of roentgenologists and radiologists. Is that correct? Mr. Villforth, have you heard of that statement?

MR. VILLFORTH: As reported in the Bureau s Bulletin, the American College of Radiology formed a group to present their views to the medical radiation committee of the Bureau, and essentially that was the recommendation of that group. I don t think that is the concensus, necessarily, of the College or the formal blessing of the College, but I think probably their recommendation. I don t know whether the College rescinded it or not; the recommendation to the Bureau from its medical radiation advisory committee has not been rescinded by the advisory committee.

DR. ALCORN: The meeting in Washington, held by the Bureau of Radiological Health in April of 1975, was the MRAC meeting, and in sum and substance, a policy statement was developed jointly in which we did not recommend routine screening of asymptomatic persons under the age of 35. We also strongly supported the point 7 BCDDP projects. It is hoped that on the basis of the analysis of the information that comes from these, the true value of screening among persons of various risk categories and ages, which is part of it, could be weighted. The age 35 group was arbitrarily picked, primarily because under the age of 35, the number of cases of breast cancer is very few. Of course, under the age of 45 there are even fewer yet. As Dr. Moskowitz mentioned, these are the people who live the longest, and the ones in which physical examination is very difficult; and since they have such a long life ahead of them, finding cancers in these individuals is a distinct advantage. It is no particular triumph to find a small cancer in a 75-year-old lady; she is probably going to live out her statistical life. The statement that we drafted will go to the Board of Chancellors for approval, and has been sent to the American Cancer Society, which supports these BCDDP projects, and to the Bureau of Radiological Health, as well as numerous others. It will be published in a policy bulletin, probably next fall. That is as much as I know about the statement.

DR. LASKY: A significant part to that statement on the screening of women under 35 concerns asymptomatic women without a family history of breast cancer.

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SESSION: RADIOACTIVITY AND THE ENVIRONMENT

Moderator: *Sherwood Davies*, New York

A STATE VIEWPOINT OF EPA DRINKING WATER RADIOACTIVITY STANDARDS
Donald E. Van Farowe, Chief, Radiation Division, Michigan Department of Public Health

THE RADIOLOGICAL IMPACT OF THE PHOSPHATE INDUSTRY - A FEDERAL PERSPECTIVE
Richard J. Guimond, Assistant to the Director for Special Projects, Criteria & Standards Division, Office of Radiation Programs, U.S. Environmental Protection Agnecy

SOLVING THE PHOSPHATE RECLAIMED LANDS PROBLEM - A STATE APPROACH
Wallace B. Johnson, Florida Department of Health and Rehabilitative Services

THE NEED FOR RADIATION CONTROLS IN THE PHOSPHATE AND RELATED INDUSTRIES
Gary F. Boothe, Division of Environment, Idaho Department of Health and Welfare

REGIONAL APPROACH TO SITING OF NUCLEAR FACILITIES
Dr. Edward Held, U.S. Nuclear Regulatory Commission

TERMINAL STORAGE OF RADIOACTIVE WASTE
Carl Kuhlman, Division of Nuclear Fuel Cycle and Production, Energy Research and Development Administration (presented by Mr. Wayne Knowles)

SESSION: TOPICAL ISSUES

Moderator: *John R. Stanton*, New Hampshire

COMPREHENSIVE RADIATION ASSESSMENT STUDY (CRAS)
James A. Blackburn, Illinois Department of Public Health

U.S. NUCLEAR REGULATORY COMMISSION'S NUCLEAR INDUSTRY STANDARDS ACTIVITIES
Craig Roberts, Division of Siting, Health, and Safeguards Standards, U.S. Nuclear Regulatory Commission

WHAT IS GOING ON IN PERSONNEL DOSIMETRY?
Caleb B. Kincaid, Bureau of Radiological Health, Food & Drug Administration

SESSION: OPEN DISCUSSION OF CURRENT EVENTS

CURRENT EVENTS: TRAINING OF STATE RADIOLOGICAL HEALTH PERSONNEL
Charles M. Hardin, National Training Coordinator, Conference of Radiation Control Program Directors

CURRENT EVENTS: THE KEER-MCGEE INCIDENT
Robert L. Craig, Radiation Protection Division, Oklahoma Department of Health

CURRENT EVENTS: TRANSPORTATION OF RADIOACTIVE MATERIALS

Andrew P. Hull, Safety and Environmental Protection Division, Brookhaven National Laboratory

CURRENT EVENTS: STATUS REPORT ON EMERGENCY PREPAREDNESS

Harold E. Collins, Office of State Programs, U.S. Nuclear Regulatory Commission

A STATE VIEWPOINT OF EPA DRINKING WATER RADIOACTIVITY STANDARDS

Donald E. Van Farowe
Chief, Radiation Division
Michigan Department of Public Health

The State Drinking Water Act, Public Law 93-523, of 1974 takes the generic form of several laws enacted by Congress in recent years. The trend is toward legal coercion of the States by Federal bureaucracy deteriorating States' rights. Proposed rules under the State Drinking Water Act were published in the FEDERAL REGISTER of August 14, 1975, to establish the EPA Radioactivity Drinking Water Standards. They indicated gross detachment from reality, and I will not comment further on the appropriateness of the 4 millirem per year limit.

The published rules consist of four parts: Maximum Contamination Levels; Analytical Methods; Monitoring Frequency; and Reporting Requirements. The maximum contaminant levels are subdivided into a mixture of concentrations, compliance criteria, and dose limits for natural and manmade radioactivity.

The standards for natural radioactivity are limited to gross alpha and radium with specific radium-226 analysis being required only if the gross alpha activity is above 5 picocuries per liter. When radium-226 concentration is above 3 picocuries per liter, radium-228 analysis is required. While these standards may not be unreasonable, the requirement to monitor all community water supplies on a 4-year basis appears unnecessary, since the radium problem in drinking water applies almost entirely to ground water supplies.

EPA once made the following statement: "Radium-226 is distributed widely in the United States, and is found frequently in ground water, particularly in the mid-West and Rocky Mountain States. Unlike the situation for ground water, radium is infrequently found in any appreciable quantity in United States surface waters. In most of the public supply systems utilizing surface water, the radium content is extremely low--less than 0.1 picocuries per liter." This statement tends to negate the need for extensive alpha monitoring. To require that all supplies using surface water be monitored is not cost effective. Radium in ground water is not a universal problem, and most high radium sources are already known. An area screening survey to confirm the problem areas would be reasonable with a continuous monitoring program for areas of supplies having high alpha and/or radium content.

A proposed radium and gross alpha monitoring program should include the following:

1. Routine monitoring of surface water in limited geographic areas where alpha and radium analysis could be important.
2. Statistically selected sites for the sampling of ground water supplies in those areas with virtually no alpha activity.
3. A resampling schedule for supplies exceeding the limits following corrective action.

The second category--manmade radioactivity--is segregated further into generally contaminated water supplies and supplies contaminated by effluents from nuclear facilities. Fallout is the manmade source of general aquatic radioactivity. Levels have been droping steadily since 1963, after the signing of the Nuclear Test Ban Treaty. Present weapons surveillance methods are sufficient to predict trends in radionuclide contamination levels. Limited area monitoring would give sufficient additional data for comparison with future air and aquatic comtamination. The objective for monitoring 100,000-person supply systems, as stated in the FEDERAL REGISTER is: "Except (sic) as noted below, mandatory monitoring for manmade radioactivity is limited to gross beta particle activity, strontium-90, and tritium in systems supplying surface water to more than 100,000 persons. Only these larger systems must monitor, since they can provide a baseline on the ambient radioactivity concentrations in most areas of the country without imposing major additional fiscal burdens on the States." Baseline data should, in my opinion, be accumulated on an area basis, rather than on a water supplying size criteria to be cost effective and to realize the best benefit/risk ratio. The selection of the supplies to be monitored should be representative of the geographical areas and contamination vulnerability.

Suggestions for the analysis on an area basis are as follows:

1. Eliminate tritium analysis, since EPA indicates that tritium levels rarely exceed 1,000 picocuries per liter, corresponding to doses of less than 0.2 milligrams per year, and will rise only as a result of contamination from local sources or nuclear bomb testing.

2. Require specific strontium-90 analysis only if gross beta activity, (with strontium-90-yttrium-90 standardization), is greater than the strontium-90 limit of 8 picocuries per liter.

The proposed monitoring schedule; quarterly analysis for gross beta, iodine-131, cesium-134, and strontium-89, and annual monitoring for tritium and strontium-90; should be changed. Iodine-131, with its short half-life and low limit should either not be sampled at all or should be sampled monthly. Monitoring for cesium should be based on cesium-137 analysis. While the limit for cesium-134 is lower, cesium-137 is more likely to be found in the environment. Specific analysis of strontium-89 and strontium-90 could be eliminated by the use of gross beta screening using strontium-90-yttrium-90 standardization.

Nuclear facility discharge data could be substituted for drinking water supply monitoring. Routine plant discharges are on a batch basis, and the best sampling locations are at the discharge. I suggest substitution of direct, continuous monitoring of the plant liquid effluent by the State in lieu of periodic grab sampling of the drinking water as the most cost effective control. I do not know whether the Nuclear Regulatory Commission agrees with that point of view or not.

The EPA selected analytical methods have been described by one of the States as unreliable, insensitive, and out of date. I have been puzzled by the enigma of inconsistent standardization of alpha and beta sources as proposed by EPA. For example, in the Handbook of Radiochemical Methods, EPA suggests that the plutonium-239 be used as the standard for gross alpha and that strontium-90-yttrium-90 be used for gross beta. Then, in the "Tentative Method for Measurement of Gross Alpha and Gross Beta Radioactivities in Environmental Waters," the standard is switched to americium-241 for alpha and cesium-137 for beta. In another publication, which appeared in 40 CFR 141, polonium-210 was used as the gross alpha standard and cesium-137 was used for beta. In the U.S. Public Health Service method 302, natural uranium was used as the gross alpha standard and cesium-137 for beta, and so on. Again, EPA, in a personal communication from the Quality Assurance Branch suggests that americium-241 be used as the alpha standard, and either strontium-90-yttrium-90 or cesium-137 as the beta standard. This just turns into a mess when it comes to trying to correlate results from one agency to another when there is not a set of standards that is recommended for procedures. I think that this is one area that we really need to work on.

Michigan's costs to perform the proposed drinking water monitoring were calculated two ways; using the EPA cost for each analysis as recorded in the FEDERAL REGISTER of August 14, 1975, and using the actual projected costs. All figures are adjusted for inflation at a modest 5 percent per year, uncompounded. The net result of this cost estimation is that based on the December 1975 draft, the initial 2-year cost, according to the EPA cost estimate, would be $34,000, or about $17,000 per year. The routine cost by 1981 would be about $19,000 per year. Based on Michigan's estimate for the same period, we have $80,000 per year as the initial 2-year cost, and $62,000 per year for the routine cost figure. You see there is a wide variation in the estimated cost--a factor of about 5. This appears throughout the cost estimate for the December 1975 version versus the Michigan Department of Public Health suggested adaptable EPA criteria--the factor of 5 remains, but if our suggestions are adopted, the costs per year are substantially reduced. For example, in 1981, according to the EPA cost estimates, it would be about $9,000 per year, and according to the Michigan Department of Public Health estimate, it would be about $55,000. In other words, I think that EPA is trying to sell the States on a bill of goods to buy something, and their figures are unrealistically low in terms of cost estimates. I would say, if you are thinking about buying this, look at the fine print.

The Federal Government may pay as much as 75 percent of this program, but this formula may be revised, resulting in a large State fiscal obligation; in other words, EPA has suggested that they might possibly pay up to 75 percent of the cost, but you do not know what is going to happen next year--it could be 10 percent of the cost, or eventually phasing out all cost support.

Finally in the matter of reports; notifications of noncompliance are to be reported with consumer bills and in the newspaper. This requirement seems to substitute public pressure for agency enforcement. The 3-month publication repeat requirement should include some State discretion considering the time for compliance on long term problems, especially since compliance failure may not be of measurable public health significance.

In conclusion then, the proposed rules have been improved significantly from the August 1975 to December 1975 draft, and the EPA has responded to the remarks of States and industry, but much further improvement is required.

DISCUSSION

DR. HULL: I just want to make one comment on the standards business. On one of the standards groups I participate in, we took the philosophy that for beta, cesium was useful. I had not thought about alpha until this moment (I had no occasion to), but I would think that americium would be useful, because if you have a gamma spectrometer around, you could very easily double check to see if you really have the activity you thought you had in the standard, or if anything has happened to it.

MR. AAROE: These standards that are about to come out - are they supposed to be effective, or are they still in draft form?

MR. GUIMOND: These standards that are going to be coming out shortly, will have an effective date of June 1977.

THE RADIOLOGICAL IMPACT OF THE PHOSPHATE INDUSTRY - A FEDERAL PERSPECTIVE

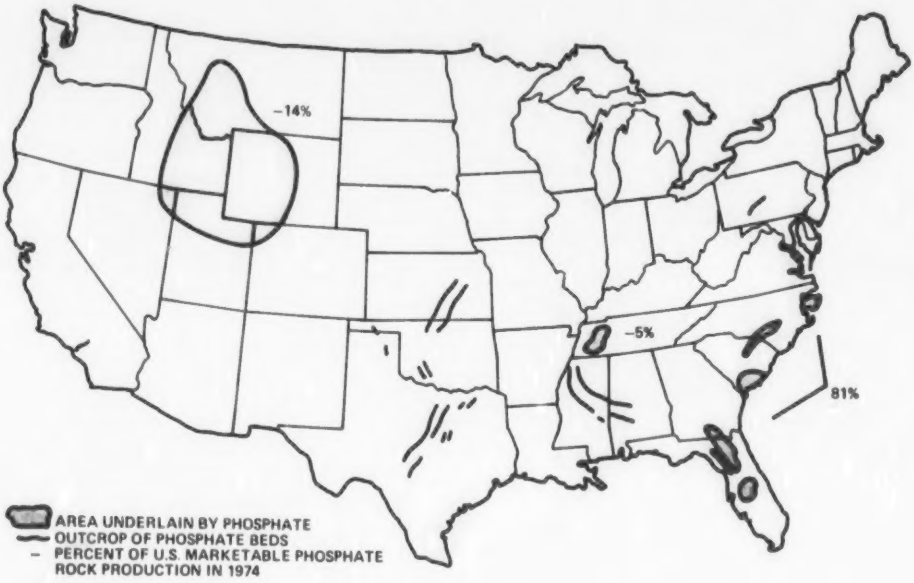
Richard J. Guimond
Assistant to the Director for Special Projects
Criteria & Standards Division
Office of Radiation Programs
U.S. Environmental Protection Agency

The Office of Radiation Programs (ORP) began its national study of the phosphate industry in June 1974. Since that time we have conducted extensive environmental sampling, analyzed hundreds of specimens, and performed numerous calculations and modeling tasks. This work has all been directed toward comprehensively characterizing the radioactivity source terms, assessing the resultant public health and environmental impact, and determining the adequacy of existing standards and controls. Throughout this period, whenever I was asked why the Office of Radiation Programs is investigating the phosphate industry, I frequently noted some cynicism or at least skepticism in the inquirer's mind. In fact, you could almost hear them say, the phosphate industry doesn't operate any nuclear reactors, x-ray equipment, or have any involvement in the production or use of medical isotopes; how could they possibly cause any adverse radiological impact on the environment?

Unfortunately, this is the attitude many people have been taking toward man's alteration of the natural radioactivity environment over the years. Of course, the phosphate industry doesn't manufacture any radionuclides or radiation producing equipment. However, the industry does annually redistribute in the environment massive quantities of naturally-occurring radionuclides through its products, byproducts, and wastes. But that is background, you say, primordial radionuclides, there is nothing you can do about it. Indeed, the industry redistributes only naturally occurring radionuclides, but whether the resultant environmental levels should be considered normal background and whether it is uncontrollable, are areas where a new perspective is needed nationwide. The phosphate industry is not the only group that mines or otherwise processes large amounts of naturally occurring radionuclides. Numerous others including the titanium, coal, and even building materials industries also belong to this category. Their potential impacts will be discussed later. For now, let us focus more closely on the phosphate industry.

PHOSPHATE INDUSTRY OVERVIEW

The mining of phosphate rock began in the United States in 1867, when a few tons of marketable rock were produced in South Carolina. Since that time, the phosphate industry in the United States has experienced tremedous growth. In 1974, the total U.S. production of marketable phosphate rock was about 46 million tons which has a market value of about 500 million dollars *(1)*. At the present, the U.S. marketable phosphate rock production accounts for about 40 percent of the total world production. About 30 percent of the U.S. production is annually exported to various countries around the world to improve crop yields. The richest U.S. phosphate deposits are in the form of marine phosphorite. These are located in Florida, North Carolina, Tennessee, and the Phosphoria Formation of Idaho, Montana, Utah, and Wyoming and depicted in figure 1.


-14%
-5%
81%
AREA UNDERLAIN BY PHOSPHATE
OUTCROP OF PHOSPHATE BEDS
- PERCENT OF U.S. MARKETABLE PHOSPHATE ROCK PRODUCTION IN 1974

SOURCES OF INFORMATION
MINERALS YEARBOOK - 1974, USBM
FINAL EIS - PHOSPHATE LEASING ON
THE OSCEOLA NATIONAL FOREST, FLORIDA 1974

Figure 1. United States phosphate deposits.

It has been recognized for several years that phosphate deposits throughout the world contain appreciable concentrations of radioactive material originating from the decay of uranium and thorium present in the ores. Previous studies of the variability of concentrations of natural uranium and thorium in the phosphate ores produced in the United States indicate that they range from 8 to 399 ppm (5.4 to 267 pCi per gram) and 2 to 19 ppm (0.4 to 4 pCi per gram), respectively *(2)*. The highest concentrations were reported in South Carolina phosphate and the lowest were in Tennessee phosphate rocks.

Generally, the uranium daughters in the ores, at least through radium-226, have been shown to be in secular equilibrium. Figure 2 illustrates the uranium decay series. To date, most of the scientific work that has been performed regarding radioactivity in phosphate related materials has been focused on determining the uranium concentration in the various phosphate formations. These studies were sparked by the quest for sources of refinable uranium usable in the nuclear power industry or for weapons production. Little emphasis has been placed on the health physics or environmental radioactivity aspects of the various industry operations. However, additional studies have recently been initiated by industry sponsored groups and other governmental groups that should be complementary to the study presently underway in the Environmental Protection Agency.

Table 1 compares the total uranium and radium-226 extracted from the earth by the phosphate industry to that from the uranium mining industry, Since the beginning of each of these mining industries, the phosphate industry has mined the equivalent of 321 thousand tons of U_3O_8, whereas, the uranium industry has mined the equivalent of 270 thousand tons *(3,4)*. While the concentration of uranium and other radionuclides in uranium industry ores are generally about 10 to 20 times those found in the phosphate industry, both groups have been adding large, comparable quantities of naturally occurring radionuclides into the

URANIUM - 238 DECAY SERIES

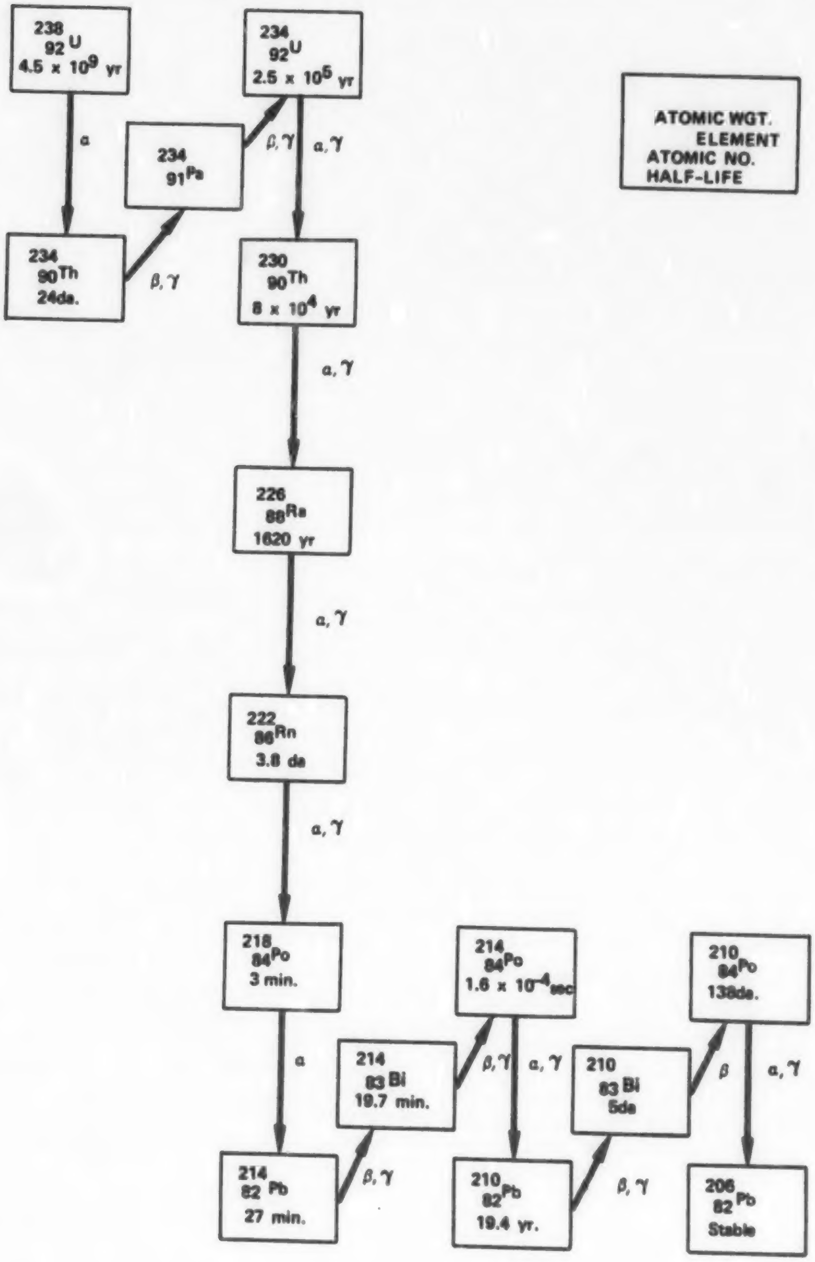

238 92 U 4.5 x 10^9 yr
α
234 90 Th 24da.
β, γ
234 91 Pa
β, γ
234 92 U 2.5 x 10^5 yr
α, γ
230 90 Th 8 x 10^4 yr
α, γ
226 88 Ra 1620 yr
α, γ
222 86 Rn 3.8 da
α, γ
218 84 Po 3 min.
α
214 82 Pb 27 min.
β, γ
214 83 Bi 19.7 min.
β, γ
214 84 Po 1.6 x 10^-4 sec
α, γ
210 82 Pb 19.4 yr.
β, γ
210 83 Bi 5da
β
210 84 Po 138da.
α, γ
206 82 Pb Stable
ATOMIC WGT.
ELEMENT
ATOMIC NO.
HALF-LIFE

Figure 2

biosphere. The majority of the phosphate rock mining in the United States has occurred in Florida, where about 87 percent of the total U.S. output was produced in 1974, whereas the total production of ore for the uranium mining industry has been distributed through several western States, with primary production from the Colorado Basin area. New Mexico has been the State providing the most uranium ore with cumulative production of about 40 percent of the total. Clearly, from these comparisons, a substantial quantity of natural radionuclides has been distributed through the Florida environment. Therefore, the EPA study has focused particular attention on assessing the industry's impact on Florida.

TABLE 1

HISTORICAL COMPARISON OF QUANTITIES OF URANIUM AND RADIUM-226 EXTRACTED BY THE U.S. URANIUM AND PHOSPHATE MINING INDUSTRIES

INDUSTRY		SHORT TONS OF ORE ($\times 10^6$)		SHORT TONS OF U3 O8 ($\times 10^3$)		CURIES OF RADIUM-226 ($\times 10^3$)	
		TOTAL THRU 1964	TOTAL THRU 1974	TOTAL THRU 1964	TOTAL THRU 1974	TOTAL THRU 1964	TOTAL THRU 1974
PHOSPHATE MINING INDUSTRY	MINE ROCK	1710	2840	193(b,c)	321(b,c)	50(a)	83(a)
	MARKETABLE ORE	531	880	56(b,c)	90(b,c)	14(a)	23(a)
URANIUM MINING INDUSTRY		58	147	147	270	38(a)	69(a)

(a) ASSUMING EQUILIBRIUM WITH THE URANIUM-238 PARENT.
(b) ASSUMING A URANIUM CONCENTRATION OF 120 PPM.
(c) NO CONTRIBUTION WAS INCLUDED FOR TENNESSEE ORE.

PHOSPHATE MINING AND BENEFICIATION

Florida land-pebble phosphate deposits are characterized by pebbles and fine phosphatic sand dispersed in a nonphosphatic sandy clay. This matrix, varying in thickness from 1 to 50 feet but averaging about 16 feet, is covered by an overburden of quartz sand and clay that averages 20 feet in thickness *(5)*.

The standard mining practice in the Florida land-pebble phosphate fields is to strip the overburden and mine the phosphate matrix with draglines as shown in figures 3 and 4. Electric-powered walking draglines with 35 to 70 cubic yard buckets work in cuts varying from 150 to 250 feet in width and from a few hundred yards to a mile or more in length. The cuts are from 50 to 70 feet deep. Overburden is stacked on unmined ground adjacent to the initial cut by means of a dragline, until successive cuts allow it to be cast into adjacent mined-out cuts. As each cut is stripped of overburden and then mined, the ore is stacked in a suction well or sluice pit that has been prepared on unmined ground. High pressure water is used to produce a slurry of about 40 percent solids from the matrix. This slurry is then pumped via pipe to the washer plant. In this manner, a typical operation will mine about 400 acres of land per year, remove 13 million cubic yards of overburden, and mine 9 million yards of matrix per year.

Similar wet mining techniques are used to extract phosphate rock in North Carolina. However, in Tennessee and the western States, dry mining techniques are employed in which the mined rock is transported to the beneficiation plant or mill by trucks or rail cars.

Figure 3. Dragline stripping overburden.

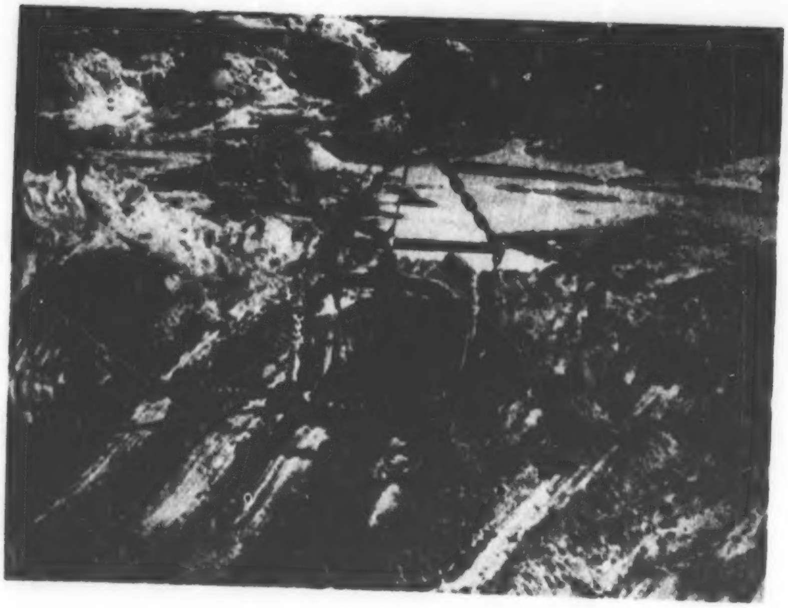


Figure 4. Dragline bucket removing matrix.

While a sizable portion of the rock mined in the western States can be utilized directly in mills without upgrading the P_2O_5 percentage, most of the Florida and North Carolina ores require beneficiation (i.e., increasing the P_2O_5 content by physical separation). The flow diagram for materials movement to and from a typical Florida beneficiation facility is shown in figure 5. The numbers in boxes are the uranium-238 concentrations and the numbers in ovals are radium-226 concentrations for the respective input and output materials *(6)*. Table 2 presents the estimated total activities of radium-226 and uranium-238 present in the mine rock and beneficiation plant products based upon the concentrations in figure 5 and 1974 U.S. production data. Of the total radium-226 and uranium present in the 1974 Florida beneficiation plant products and wastes, approximately 42 percent was in the marketable rock, 48 percent was in the slimes, and the remainder was in the sand tailings.

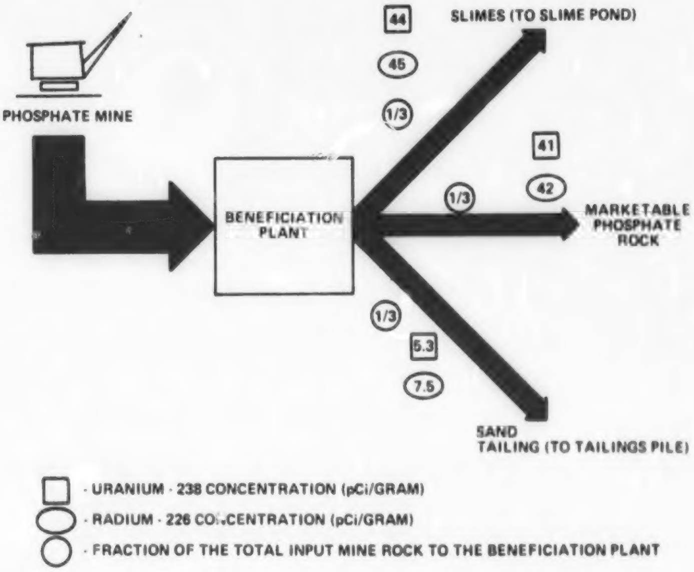

PHOSPHATE MINE
BENEFICIATION PLANT
44
45
1/3
SLIMES (TO SLIME POND)
41
42
1/3
MARKETABLE PHOSPHATE ROCK
1/3
5.3
7.5
SAND TAILING (TO TAILINGS PILE)
☐ - URANIUM - 238 CONCENTRATION (pCi/GRAM)
⬭ - RADIUM - 226 CONCENTRATION (pCi/GRAM)
○ - FRACTION OF THE TOTAL INPUT MINE ROCK TO THE BENEFICIATION PLANT

Figure 5. Typical Florida phosphate mining and beneficiation operation.

TABLE 2

ESTIMATED TOTAL RADIUM-226 AND URANIUM 238 ACTIVITIES IN FLORIDA PHOSPHATE MINE PRODUCTS AND WASTES FOR 1974

MATERIAL	1974 PRODUCTION ($\times 10^6$ TONS)	RADIUM-226 (CURIES)	URANIUM-238 (CURIES)
MINE ROCK	142.1		
MARKETABLE ROCK	37.0	1398	1387
SLIMES[a]	39.0	1590	1569
SAND[b] TAILINGS	60.1	409	289
TOTAL	136.1	3397	3245

(a) BASED ON 2110 POUNDS OF SLIMES PRODUCED PER TON OF PRODUCT
(b) BASED ON 3250 POUNDS OF SAND TAILINGS PRODUCED PER TON OF PRODUCT

In beneficiation, water is used for processing, in addition to being used as a transportation medium. Both fresh water from deep wells and reclaimed water from slime settling ponds are used by the phosphate industry. Approximately 10,000 gallons of water are necessary to produce one ton of marketable phosphate rock. As the mining progresses, mined-out areas are used for the disposal of tailings and slimes, in addition to overburden. Some of the sand tailings and overburden is used to construct retaining dams in mined-out areas, behind which phosphatic clay slimes settle and dewater.

Several slime ponds have discharges to the environment. The discharge quantities depend upon the facility's degree of recycle, overall water consumption, and local precipitation. Since most of the radioactivity in the waste products of beneficiation is present in the slimes, this could pose potential problems to receiving streams if the radioactivity was not removed prior to discharge. To examine this aspect, the concentration of radium-226 was determined for slime discharges and effluent discharges from seven mine and beneficiation plants. This data is illustrated in Table 3. The concentration of dissolved radium-226 in slime discharges was less than 5.0 picocuries per liter at all seven facilities. The concentration of radium-226 in the undissolved fraction varied greatly and was highly dependent on the total suspended solids in the slime discharge. The radium-226 concentrations in picocuries per gram of the undissolved fraction at all seven facilities are in the same order of magnitude emphasizing the importance of the total suspended solids concentration in determining the total concentration of radium-226 in picocuries per liter in the slime discharge. Although no chemical process is used to treat the discharge from the slime ponds, low dissolved radium-226 concentrations were observed in the effluents. This is attributed to the generally low dissolved radium-226 concentrations in the slime discharge.

TABLE 3

RADIUM-226 CONCENTRATIONS IN PHOSPHATE MINE EFFLUENTS

FACILITY	HEAVY SLIME DISCHARGE			EFFLUENT DISCHARGE			
	DISSOLVED	UNDISSOLVED		DISCHARGE POINT	DISSOLVED	UNDISSOLVED	
	pCi/LITER	pCi/LITER	pCi/gm		pCi/LITER	pCi/LITER	pCi/gm
1	0.82	10.2	21.3	A	0.66	0.26	17.3
				B	0.52	0.28	21.5
				C	0.68	0.28	18.7
2	4.8	1074	72.6	A	0.02 0.34	0.56 1.1	31.1 52.4
3	2.0	97.6	30.5	A	2.2	0.74	38.9
4	0.6	37.7	9.8	A	0.24	0.74	28.5
5	2.2	520	52.0	–	–	–	–
6	1	2248	33.6	–	–	–	–
7	0.96	725.5	15.0	A	1.01	0.14	7.0

The total concentration of radium-226 in every effluent discharge sample analyzed was less than 3.0 picocuries per liter. Comparison of the slime discharge and effluent discharge concentrations indicate that no specific reduction in soluble radium-226 is predictable from the data obtained at the seven facilities. This is understandable since present treatment of the slimes involves only settling of solids and consequently no appreciable precipitation of soluble radium-226 would be expected. The reduction of total radium-226 from the slime discharge to the effluent discharge ranged from 92 percent to greater than 99.9 percent in the facilities studied. This was primarily due to removal of suspended solids containing large amounts of radium-226. Therefore, because of the significance of the contribution of the radium-226 contained in the suspended solids to the total concentration of radium-226 observed in either the slime or effluent discharge, great reductions in suspended solids levels between the slime discharge and the effluent will result in corresponding reductions in radium-226 concentrations.

Based on this information, it is concluded that practicable control technology is available to readily limit total radium-226 discharges to surface waters to less than 3-4 pCi per liter. Actual estimation of population dose resulting from such a discharge will depend upon the total discharge, the stream characteristics, the number of mines discharging to the stream, and the downstream population using it for potable water. Recognizing these parameters, it is highly unlikely that discharges from mines would result in radium-226 concentrations greater than 0.25 pCi per liter above normal to downstream users *(7)*.

PHOSPHATE MILLING AND MANUFACTURING

The marketable phosphate rock can be processed by either of two types of facilities, the wet process phosphoric acid plant or the electric furnace plant.

Wet Process Phosphoric Acid Plants

In the wet process phosphoric acid plant, the raw materials are ground phosphate rock, 93 percent sulfuric acid, and water. Phosphate rock is mixed with the sulfuric acid after the acid has been diluted with water. This reaction produces phosphoric acid and gypsum. Following the reaction in the attack vessel, the mixture is filtered to separate the gypsum from the phosphoric acid (approximately 30 percent P_2O_5). The gypsum is pumped as a slurry to a large pile near the facility where it is allowed to dewater (see Figs. 6 and 7). Since approximately 4.5 tons of gypsum are produced per ton of phosphoric acid, a large phosphoric acid plant would produce about 2.7 million tons of gypsum per year.

The two other major products are triple superphosphate and ammonium phosphate fertilizers. Triple superphosphate is produced by reacting phosphoric acid and ammonia. All of these processes are graphically presented in figure 8 along with their corresponding radioactivity concentrations. The numbers in boxes indicate the uranium-238 concentrations and the numbers in ovals are the radium-226 concentrations in each material.

Gross radioactivity balancing of the input phosphate rock and the product phosphoric acid and phosphogypsum indicates that approximately 1 percent of the radium-226, and 80 percent of the uranium is dissolved during the acidulating by sulfuric acid. The numbers are quite similar to radium-226, uranium, and thorium dissolution by the acid leach process of milling uranium ore *(8)*. This

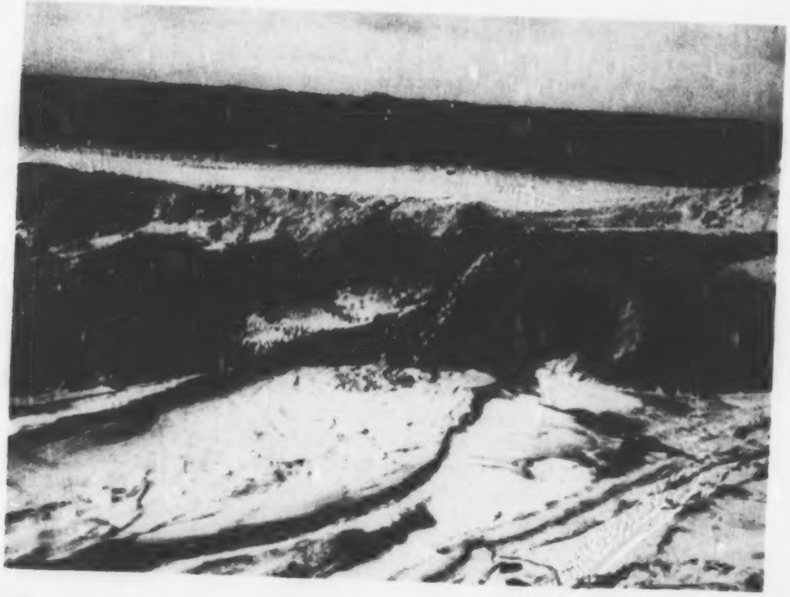


Figure 6. Gypsum slurry released at the top of the gypsum pile.

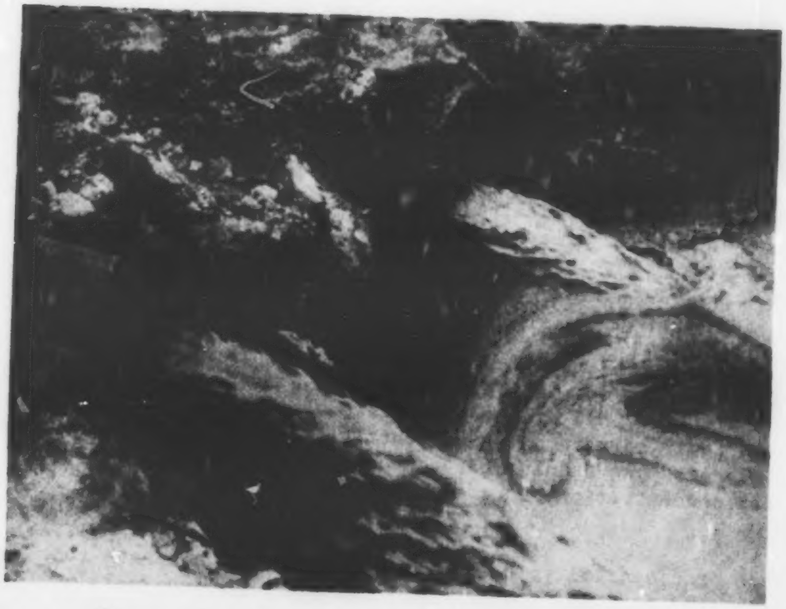


Figure 7. Gypsum slurry dewatering.

is not surprising since similar techniques and chemicals are used in both industrial processes.

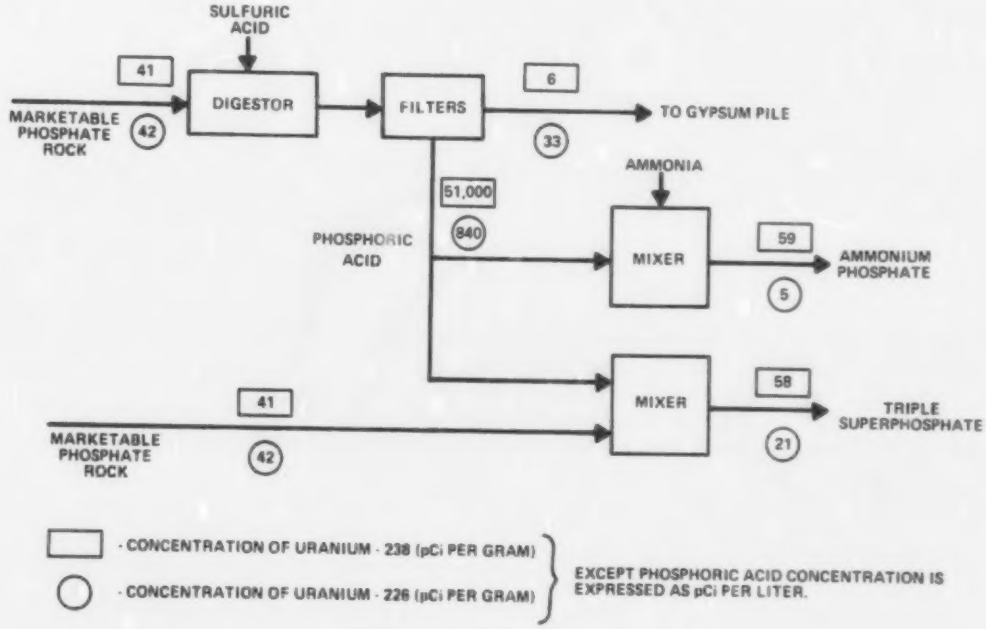

SULFURIC ACID
41
42
MARKETABLE PHOSPHATE ROCK
DIGESTOR
FILTERS
6
33
TO GYPSUM PILE
AMMONIA
51,000
840
PHOSPHORIC ACID
MIXER
59
5
AMMONIUM PHOSPHATE
MIXER
58
21
TRIPLE SUPERPHOSPHATE
41
42
MARKETABLE PHOSPHATE ROCK
▭ - CONCENTRATION OF URANIUM - 238 (pCi PER GRAM)
○ - CONCENTRATION OF URANIUM - 226 (pCi PER GRAM)
EXCEPT PHOSPHORIC ACID CONCENTRATION IS EXPRESSED AS pCi PER LITER.

Figure 8. Production flowsheet for a wet-process phosphoric acid plant.

Individual samples of phosphoric acid displayed a great variation of radium-226 concentration ranging from a few hundred to greater than one thousand picocuries per liter. The variation was not observed to be a function of solids content or P_2O_5 concentration. The average of seven phosphoric acid samples was 840 pCi/liter of radium-226. This translates to a concentration of less than 1 pCi per gram of 52 percent phosphoric acid, whereas uranium concentration was about 51,000 pCi per gram.

Ammonium phosphates (DAP and MAP) were observed to have radium-226 concentrations of about 5 pCi per gram. Uranium concentrations were a factor of 10 greater than the radium-226 concentrations. The relatively low radium-226 concentration and much higher uranium concentration is attributed to the fact that production of ammonium phosphates uses only ammonia and phosphoric acid with no direct reaction with phosphate rock. Consequently, the bulk of the radioactivity introduced to the reaction comes from the phosphoric acid which is enriched with uranium and deficient in radium-226 due to the partition by removal of the phosphogypsum.

Triple superphosphate (TSP) contained about 4 times as much radium-226 and about the same concentration of uranium as ammonium phosphate fertilizer. This is because triple superphosphate is produced by acidulating phosphate rock with phosphoric acid. Therefore, the product, triple superphosphate, would be expected to comprise activities of radium-226, and uranium, corresponding to the activities in the reactants, phosphate rock and phosphoric acid, which display markedly different radium-226, and uranium concentrations.

In order to estimate the total activities of radium-226 and uranium in the wet process phosphoric acid plant products and byproducts, 1973 production data (1974 data is not yet available) was obtained and used in conjunction with the material radioactivity concentrations shown in figure 8. The resulting total activity estimates are shown in Table 4 *(9)*.

TABLE 4

ESTIMATED TOTAL RADIUM-226 AND URANIUM-238 ACTIVITY IN PHOSPHATE FERTILIZER PRODUCTS AND BYPRODUCTS BASED ON 1973 PRODUCTION DATA[a]

MATERIAL	PRODUCTION		RADIUM-226 (CURIES)	URANIUM-238 (CURIES)
	(x 10^6 TONS)	(x 10^6 TONS P_2O_5)		
NORMAL SUPERPHOSPHATE	3.4	0.62	77	77
TRIPLE SUPERPHOSPHATE	3.7	1.72	69	190
AMMONIUM PHOSPHATES	5.8	2.67	30	330
PHOSPHORIC ACID	11[c]	5.62	5.5	600
GYPSUM	25.3		760	140

(a) WET PROCESS PRODUCTION USING FLORIDA ORE
(b) BASED ON 4.5 TONS GYPSUM PER TON P_2O_5
(c) ASSUMING 50 PERCENT P_2O_5 ACID

Approximately 80 percent of the product radium-226 activity is contained in the phosphogypsum. Although the radium-226 concentrations of normal superphosphate and triple superphosphate are similar to that of the phosphogypsum, the bulk magnitude of the phosphogypsum produced is sufficient to outweigh the individual contributions of the other products *(10)*. Phosphoric acid contributes a major portion of the total uranium activity. It is emphasized that the columns are not directly additive to determine the total radioactivity in the products because some of the activity reflected in the phosphoric acid is also accounted in the ammonium phosphate and triple superphosphate estimates because phosphoric acid is used to produce these products. From these estimates, it is evident that a sizable inventory of radioactivity is present in the phosphoric acid plant products and byproducts.

About 80 percent of the marketable phosphate rock used in the United States goes into the production of fertilizer. Estimating the amount of radioactivity distributed through the various regions of the United States is difficult because these primary phosphate fertilizers are frequently mixed and blended to form a variety of commercial fertilizers. It is difficult to trace these blends to determine if they originated from normal superphosphate, triple superphosphate, ammonium phosphate, or phosphoric acid. Recognizing the information deficiency in estimating radioactivity distribution among the States, the approximate amount of distribution can be inferred from Table 5 which gives the 1974 U.S. phosphate fertilizer consumption by State. The total U.S. consumption was about 5.07 million tons P_2O_5. Approximately 52 percent of this was used in the north central States, thus emphasizing the potential in that region for crop uptakes and soil runoff to surface and ground waters *(11)*.

Table 5

1974 U.S. Phosphate Fertilizer Consumption by State

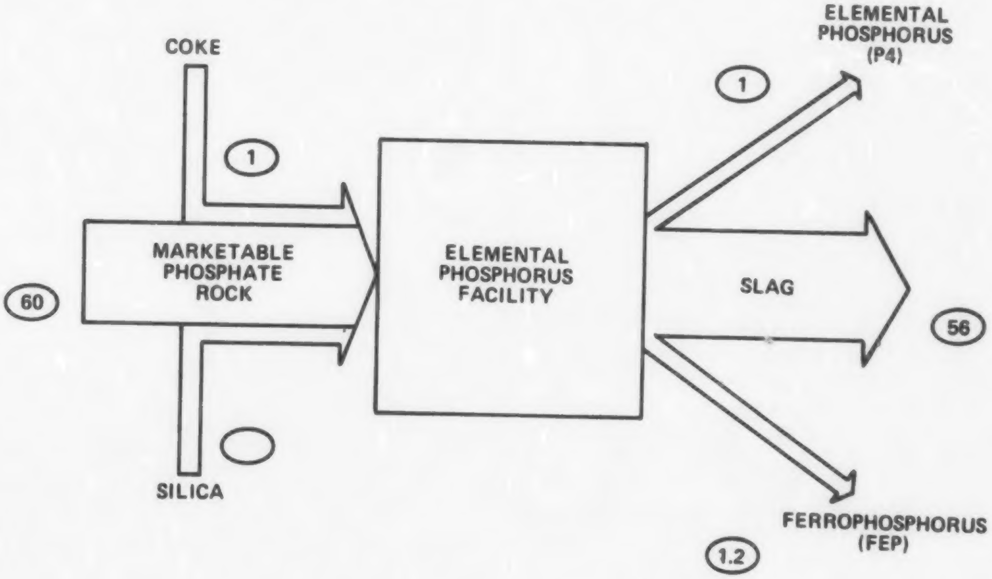
Rank	State	Thousand Tons P_2O_5	Rank	State	Thousand Tons P_2O_5
1	Illinois	478	26	Washington	71
2	Iowa	398	27	Idaho	69
3	Texas	296	28	Virginia	69
4	Indiana	292	29	Louisiana	69
5	Ohio	271	30	South Dakota	62
6	Minnesota	268	31	Montana	61
7	Missouri	189	32	Maryland	45
8	California	183	33	Oregon	45
9	Kansas	176	34	Colorado	44
10	Georgia	153	35	Arizona	36
11	North Carolina	152	36	New Jersey	20
12	Michigan	148	37	Utah	19
13	Wisconsin	139	38	Maine	18
14	Nebraska	136	39	Delaware	16
15	Alabama	113	40	New Mexico	16
16	North Dakota	110	41	Hawaii	16
17	Kentucky	108	42	West Virginia	10
18	Oklahoma	105	43	Puerto Rico	9
19	Florida	104	44	Wyoming	8
20	Pennsylvania	93	45	Vermont	7
21	Tennessee	91	46	Massachusetts	7
22	New York	90	47	Connecticut	5
23	Mississippi	88	48	Rhode Island	3
24	Arkansas	80	49	Nevada	2
25	South Carolina	75	50	New Hampshire	2
			51	Alaska	.4
				TOTAL	5070

Turning from the products back to the environmental aspects around the phosphoric acid plant, we find that each wet process phosphoric acid plant incorporates a large cooling pond (~500 acres) of contaminated water for recycle in the plant. During periods of excess rainfall it becomes necessary to discharge water from these ponds to nearby streams. Field studies were conducted at several such facilities to determine the extent to which the discharge practices introduced radioactivity to the surface streams. Raw process water was found to contain from 55 to 86 pCi per liter total radium-226 and from 400 to 1825 pCi per liter of uranium-238. This data showed that, in the process waters, the radionuclides were substantially out of equilibrium. This is because the uranium was dissolved preferentially over radium-226 by the acidulation and filtration step where the uranium entered the process water.

To prepare process water for discharge to the environment, the pH of the water must be increased from its normal 1.5-2.0 to 6-9. To do this, slaked lime is normally added to the discharge water in a step called "double liming." Our studies have shown that this treatment is highly effective in removing radionuclides from the discharge. Radium-226 removal of greater than 96 percent was observed in all situations studied. Corresponding reductions in uranium and thorium were found. Therefore use of this treatment allows minimization of radionuclides entering the environment through liquid discharges.

Elemental Phosphorus Facilities

In the thermal processing of phosphate rock, silica and coke are added and this mixture is electrically reduced to form elemental phosphorus. Ferrophosphorus and calcium silicate slag byproducts are also produced in this process. Present data indicates that most of the radioactivity enters this facility in the phosphate rock and leaves the facility in the slag. Figure 9 illustrates radium-226 concentrations in materials at an elemental phosphorus plant using Florida ore. Although the data is yet incomplete, there are indications that significant quantities of Po-210 may be emitted from these facilities during calcining or furnace operations. In this respect, calcining operations at wet process phosphoric acid plants may also be volatilizing Po-210 and releasing it to the environment.


ELEMENTAL PHOSPHORUS (P4)
COKE
1
1
MARKETABLE PHOSPHATE ROCK
60
ELEMENTAL PHOSPHORUS FACILITY
SLAG
56
SILICA
FERROPHOSPHORUS (FEP)
1.2

○ - CONCENTRATION OF RADIUM - 226 (pCi PER GRAM)

* - UTILIZING FLORIDA PHOSPHATE ROCK

Figure 9. Production flowsheet for elemental phosphorus facility* (The size of the arrows depict the approximate materials mass flow).

RECLAIMED PHOSPHATE LAND

On the basis of the Agency's past experience evaluating the use of uranium mill tailings as a construction material, it was believed that structures built on reclaimed phosphate lands that contain elevated radium-226 concentrations could pose potential indoor radon problems. Therefore, to evaluate this aspect, in June 1975, the Office of Radiation Programs in conjunction with the Florida Department of Health and Rehabilitative Services and the Polk County Health Department, began a study to determine the radiological significance of living and working in such structures. Preliminary data from this study showed elevated indoor radon daughter levels in some structures built on reclaimed lands as compared to structures built on unmined soil *(12)*. As data is continuing to be evaluated, the existence of elevated levels in some of these structures is being supported. The data on these structures is compared to the Surgeon General's Guidelines in Table 6. In this respect the Surgeon General's Guidelines are used only as an evaluation tool and not as an applicable standard *(13)*.

Table 6

FLORIDA INDOOR RADON DAUGHTER LEVELS AS COMPARED TO THE SURGEON GENERAL'S GUIDELINES

(FEBRUARY 1976)

RECLAIMED LAND STRUCTURES (N=12)

$\geq .05$ WL : 33-1/3%
$.05 > x \geq .01$ WL : 33-1/3%
$< .01$ WL : 33-1/3%

NON-RECLAIMED LAND STRUCTURES (N=9)

$\geq .05$ WL : 0
$.05 > x \geq .01$ WL : 22
$< .01$ WL : 78%

As a result of the Agency's preliminary data, the Administrator recommended to the Governor of Florida that "as a prudent interim measure that the start of construction of new buildings on land reclaimed from phosphate mining areas be discouraged."

The Environmental Protection Agency is presently acquiring information for the development of an acceptable radiation guide applicable to the Florida situation. An easy method of field measurement is also needed for evaluating undeveloped land in order to judge whether structures built on the land would be within the radiation guide. To accomplish this latter objective, a correlation is necessary between indoor radon daughter levels and some readily measurable parameter, such as external gamma radiation levels, the soil radium-226 concentrations, or the emanation rates of radon-222 from the soil. Until a final acceptable radiation guide and a correlation are established, the Agency has recommended the use of an interim guide. This interim guide will enable screening of proposed construction sites to determine their likelihood of posing radon daughter problems in structures built on them.

The interim recommendations were conservatively based on the Agency's present data, which is shown in figure 10, information obtained from investigators of the potential hazard associated with the use of uranium mill tailings in several western States, the consideration of the Surgeon General's Guidelines for remedial action in Grand Junction, Colorado *(14)*. The interim recommendations provided to the State of Florida were as follows:

INTERIM RECOMMENDATIONS FOR GAMMA EXPOSURE LEVELS
AT NEW STRUCTURE SITES ON FLORIDA PHOSPHATE LANDS

Average External Gamma Radiation Level	Recommendations
Equal or greater than 10 μR/hr	Construction should be delayed pending study or acceptable control technology should be instituted to preclude indoor radon daughter problems.
Less than 10 μR/hr	Construction may be initiated.

OTHER PHOSPHATE ISSUES

This paper has addressed the major aspects of the phosphate industry which the Office of Radiation Programs has studied and evaluated to date. Other aspects that we are now addressing or will investigate in the future include:

1. The positive and negative environmental impact of uranium recovery from phosphate materials as well as the potential increase in uranium reserves.
2. The radiological impact of using phosphate byproducts as construction materials.
3. The uptake of radionuclides by selected crops due to fertilizer usage or growing on reclaimed lands.
4. The impact of polonium-210 and other radionuclides through the atmospheric pathway.

The results of these studies will determine the need for additional radiation protection standards and guides in these areas.

OTHER INDUSTRIES REDISTRIBUTING NATURALLY RADIOACTIVE MATERIALS

As I previously noted, the presence of elevated concentration of naturally occurring radionuclides is not unique to the phosphate industry. Consequently, the Office of Radiation Programs has efforts directed at the assessment of the environmental impact of other industries as well as the development of standards and guides for these industries, where appropriate.

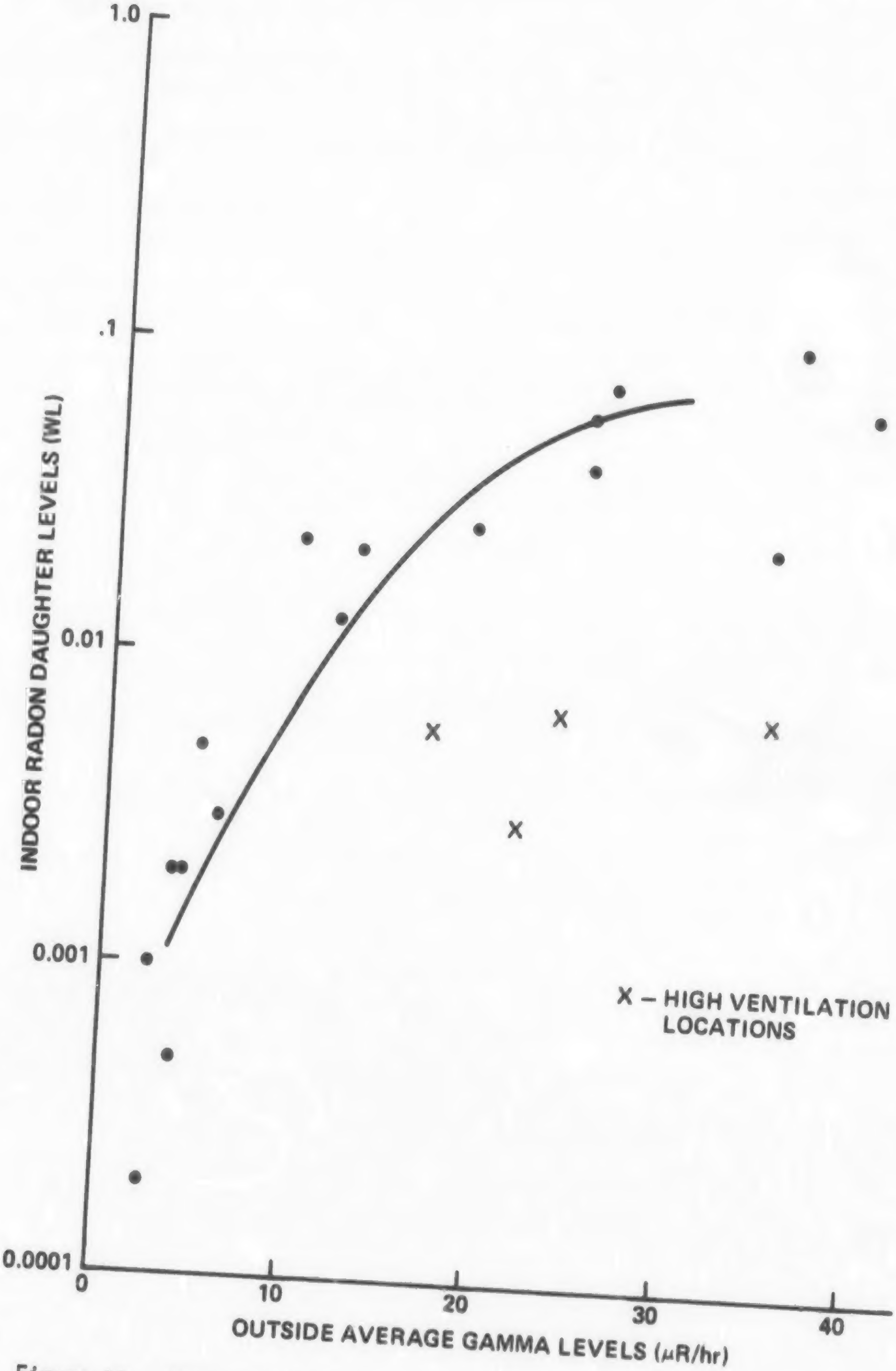


Figure 10. Observed indoor radon daughter levels as a function of outdoor average gamma radiation levels for data collected as of February 1976.

In general, the industries potentially redistributing significant amounts of naturally occurring radionuclides can be grouped into three categories:

1. Mineral extraction industries - these include the phosphate, uranium, coal, titanium, copper, and rare earth mining and milling industries.
2. Energy production industries - these include coal-fired power plants and geothermal power plants.
3. Consumer oriented industries - these include construction materials, potable water, and selected uses of geothermal energy.

At the present time the primary focus of EPA's studies are in the areas of uranium mining and milling, phosphate mining and milling, and construction materials. However, increased attention is being directed toward western coal utilization, geothermal applications, and potable water. Future efforts will be directed in these and other areas where significant potential health problems can be demonstrated.

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12. Preliminary findings-Radon daughter levels in structures constructed on reclaimed Florida phosphate land, Office of Radiation Programs, Environmental Protection Agency, Technical Note ORP/CSD-75-4, September 1975.

13. Code of Federal Regulations, Title 10, Part 12, Grand Junction remedial action criteria, December 1972.

14. Letter to E. Carlton Prather, M.D., Director, Division of Health, State of Florida from W.D. Rowe, Ph.D., Deputy Assistant Administrator for Radiation Programs, Environmental Protection Agency, January 22, 1976.

DISCUSSION

MR. AAROE: What happens to this horrendous quantity of gypsum?

MR. GUIMOND: At the present time, this horrendous quantity of gypsum is stored back of all these phosphoric acid plants in the United States. They have mountains of it, similar to the uranium mining tailings piles. A typical phosphoric acid plant would have a pile in back of it covering maybe 200 to 300 acres in size and from 75 to 150 feet high. They don't use it for much else. There are some uses in North Carolina and California; they do use gypsum for agricultural purposes. The North Carolina gypsum is used widely in growing peanuts; about 70 percent of the peanuts grown in Virginia, North Carolina, and other States use this as a soil amendment. Much of the gypsum produced in California is used as soil amendment. All of the rock that is sent to Japan or several of the European countries, because of the storage problem that they have, they use it to make wallboard. We have acquired numerous samples of wallboard made in Japan from this material and are presently evaluating them for their potential indoor radon daughter levels. To the best of our knowledge, at the present time, none of this has been imported into this country.

DR. TAYLOR: Have you made any measurements of the backgound radiation in areas where there are known underbodies of phosphate rock, but where the ground itself has been undisturbed?

MR. GUIMOND: Yes, to some degree we have. Are you talking of gamma measurements, or other types of measurements? For example, we have made gamma measurements in those instances, plus we have, where a structure might have existed, in such a situation, we have examined radon daughter levels on structures that might have been built on such lands.

DR. TAYLOR: How do those numbers run, in terms of natural background levels in nonphosphate areas?

MR. GUIMOND: Generally, in Florida, if you are outside a phosphate area, the background is extremely low; on the order of 5 microroentgens per hour. If you are into the region of phosphate, where there is phosphate material near the surface, you could be running gamma levels as high as 80 microroentgens per year.

DR. TAYLOR: You really have the chance then for "The Grand Experiment." We don't know anything about low-level radiation effects. Why don't we move a few thousand people into one of these areas, let them live there for a generation or two, maybe we can learn something.

SOLVING THE PHOSPHATE RECLAIMED LANDS PROBLEM - A STATE APPROACH

Wallace B. Johnson
Florida Department of Health and Rehabilitative Services

Man has been exposed to radioactivity and the dose arising therefrom and has been expounded in some detail by K.Z. Morgan and others. Table 1 is adapted from Morgan and Turner's "Principles of Radiation Protection." It can be seen that considerable variation in dose rates exists in a variety of environments over the world. Morgan reports external whole body exposure to range from 70-150 mrad/year for normal regions near sea level, but exposures up to 802 mrad/year were reported for certain areas of India that are rich in deposits of monazite sands. There are three principal pathways by which man is exposed to radiation from natural radioactivity: (1) External, whole body exposure, (2) Ingestion of radioactive materials; and (3) Inhalation of radioactive materials.

About 340 nuclides have been found in nature of which about 70 are radioactive and are found mainly among the heavy elements. All elements having an atomic number greater than 80 possess radioactive isotopes and all isotopes of elements heavier than number 82 are radioactive (1). Three families of radioactive isotopes of heavy elements account for much of the radioactivity to which man is exposed. These are the uranium series (derived from uranium-238), the thorium series (derived from thorium-232), and the actinium series (derived from uranium-235) (see Figs. 1 and 2).

Uranium is found in most rocks and soils. Typical concentrations range from 4.0 ppm in normal granite to 120 ppm in Florida phosphate rock (some authors report concentration of up to 250 ppm). Other sedimentary rocks are reported to contain about 1.2 ppm uranium (1). (One hundred ppm is equivalent to about 70 pCi natural uranium per gram.)

Because uranium isotopes are alpha emitters they, of themselves, do not contribute to the gamma ray background, and they are present (usually) in too low a concentration to contribute significantly to the internal dose delivered to humans (1). From the point of view of dose delivered to human beings, the isotope radium-226 and its daughter products are of greatest interest. It is reported that 100 ppm uranium in phosphate ore is equivalent to 68 pCi natural uranium per gram of material. Since natural uranium contains three isotopes having mass numbers 234, 235, and 238, content by mass number would be 33.3 pCi/gram uranium-238, 33.3 pCi/gram uranium-234, and 1.5 pCi/gram uranium-235 (2). This is of importance because radium-226 will be in equilibrium with uranium-238, uranium-234 (33.3 pCi/gram each) rather than the natural uranium.

When radium-226 decays by alpha emission, it transmutes to its daughter, radon-222, an inert gas having a half-life of 3.8 days. For purposes of this report no consideration will be given to the 54-second half-life radon-220. Phosphate deposits in Florida would be expected to contain on the order of 33 to 50 pCi/gram of radium-226.

Distribution of these radioactive isotopes is widespread in Florida (Fig. 3). The presence of natural uranium in the State is largely associated with deposits of phosphate rock. Approximately one-third the world's output and three-fourths of the United States' production of phosphate comes from Florida. Over 90 percent of the phosphate mined in Florida is used in agriculture, primarily in production of fertilizer (Fig. 4).

Table 1. Exposure to man from natural background radiation (mrad/year)

Type of Exposure	Mean Dose to Gonads (mrad/year)	Mean Dose to Bone	Mean Dose to Lungs
Internal from			
K40	18-22	7-11	15
Ra-226		3-6.7	0.5
Ra-228		3	
Pb-210		2	
C-14	0.7-1.8	1.3-1.6	
Internal from			
Rn-220 Rn-222			
Rn-220 Wooden House)	Thoron		2.3-45
Rn-220 Brick House)			2.7-210
Rn-220 Concrete House)			3.0-290
Rn-222 Wooden House)	Radon		1.3-39
Rn-222 Brick House)			5.7-120
Rn-222 Concrete House)			4.0-140
External			
U-238 Series			
Normal Regions	28-82	Approximately same as for gonads	
Th-232 Series			
Granite Regions	162	" "	"
K-40			
Monazite Region (India)	802	" "	"
Monazite Region (Brazil)	287	" "	"
External			
Cosmic Ray (0°)			
Sea Level	23-33		
10,000 feet	50-89		
Total for	100 Av.	100 Av. (180 mrem)	200 Av. (1100 mrem)
Normal Regions	70 Min.	70 Min.(140 mrem)	70 Min.(1100 mrem)
near Sea Level	150 Max.	150 Max.(250 mrem)	570 Max.(4500 mrem)

(mrem) based on RBE of 10 for alpha

(Adapted from Principles of Radiation Protection. Morgan and Turner. John Wiley and Sons, 1967.)

URANIUM - 238 DECAY SERIES

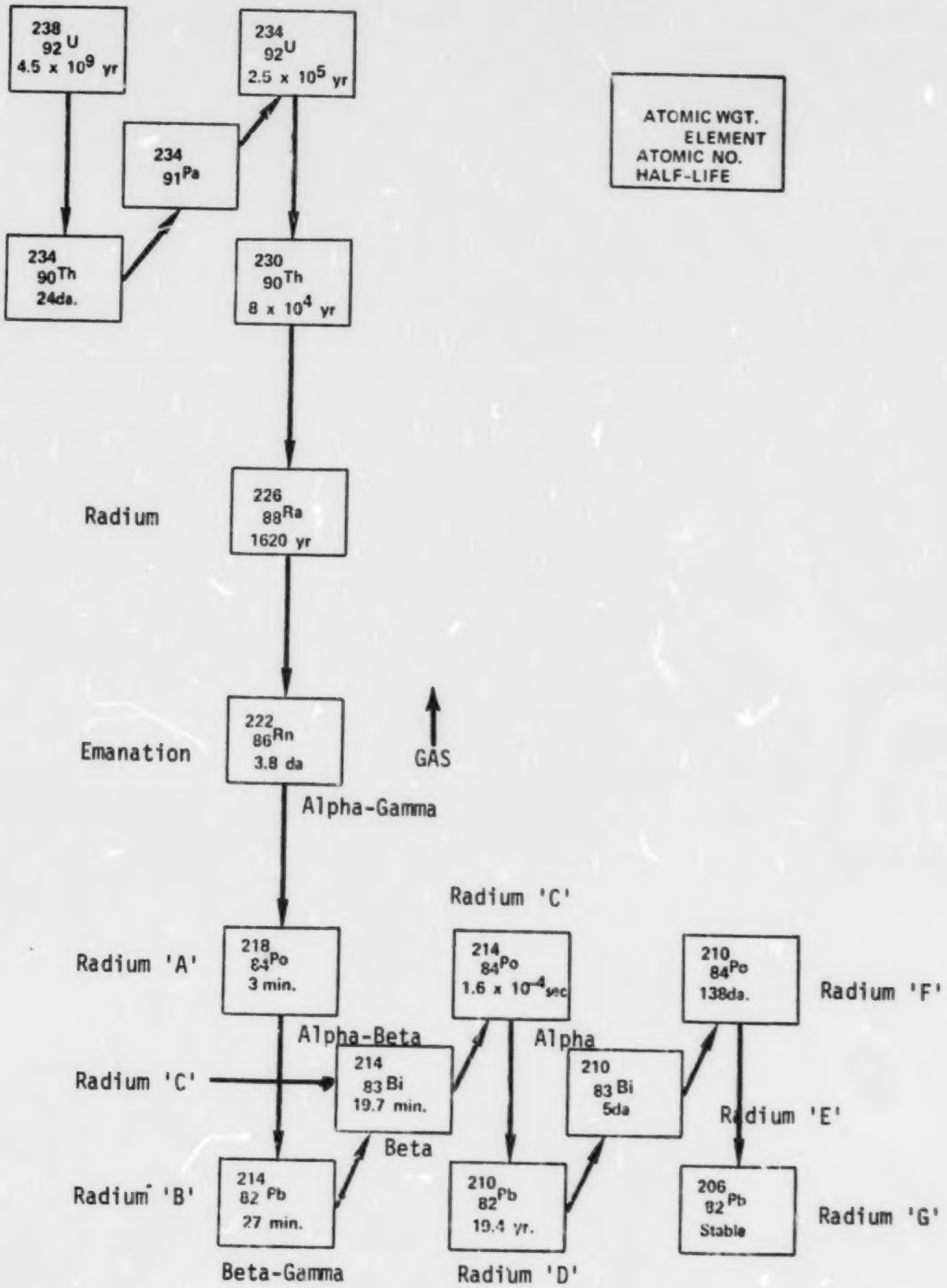

238 92 U 4.5 x 10^9 yr
234 92 U 2.5 x 10^5 yr
ATOMIC WGT.
ELEMENT
ATOMIC NO.
HALF-LIFE
234 91 Pa
234 90 Th 24da.
230 90 Th 8 x 10^4 yr
Radium
226 88 Ra 1620 yr
Emanation
222 86 Rn 3.8 da
GAS
Alpha-Gamma
Radium 'C'
Radium 'A'
218 84 Po 3 min.
214 84 Po 1.6 x 10^-4 sec
210 84 Po 138da.
Radium 'F'
Alpha-Beta
Alpha
Radium 'C'
214 83 Bi 19.7 min.
210 83 Bi 5da
Radium 'E'
Beta
Radium 'B'
214 82 Pb 27 min.
210 82 Pb 19.4 yr.
206 82 Pb Stable
Radium 'G'
Beta-Gamma
Radium 'D'

Figure 1

THORIUM - 232 DECAY SERIES

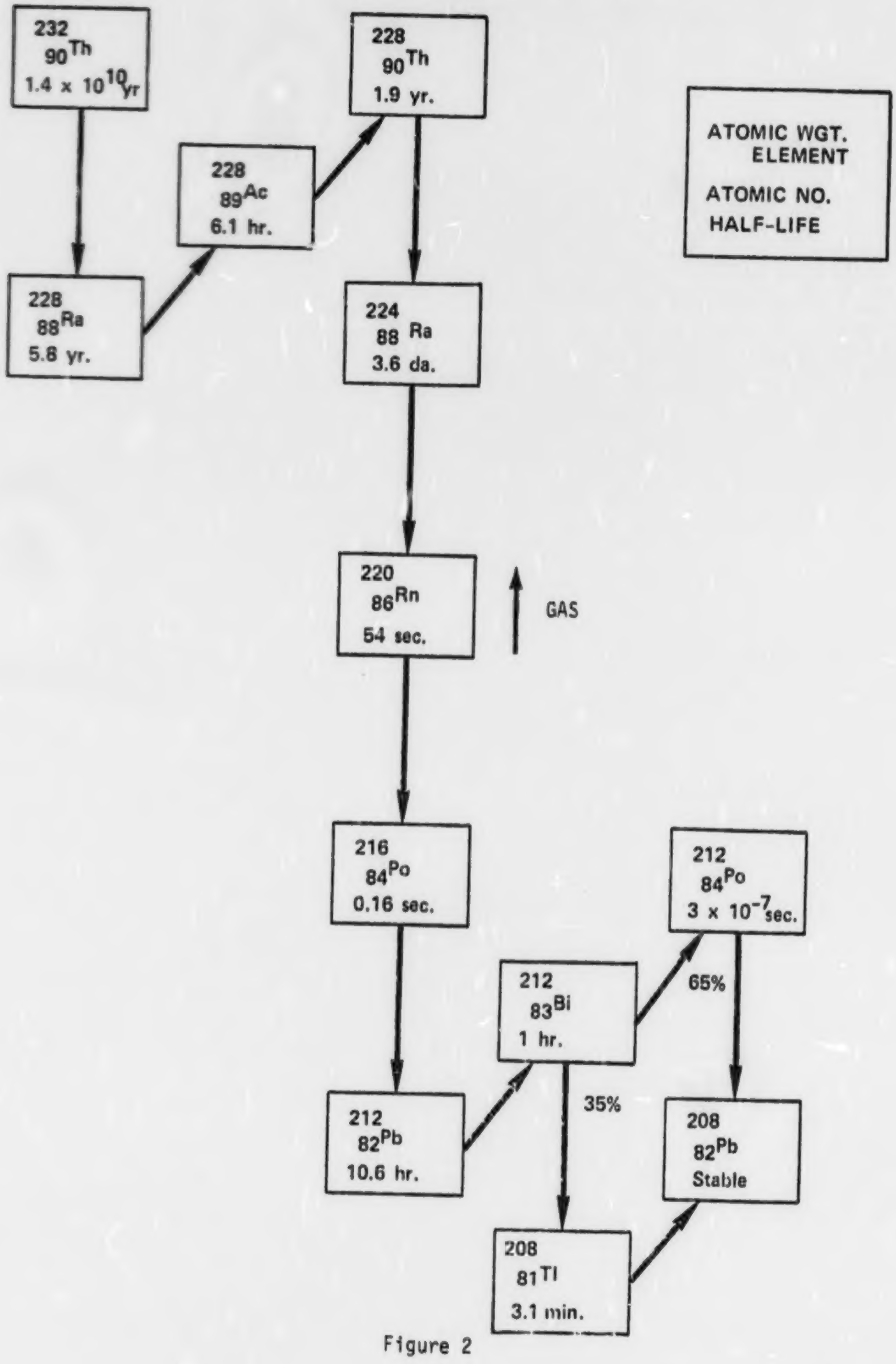
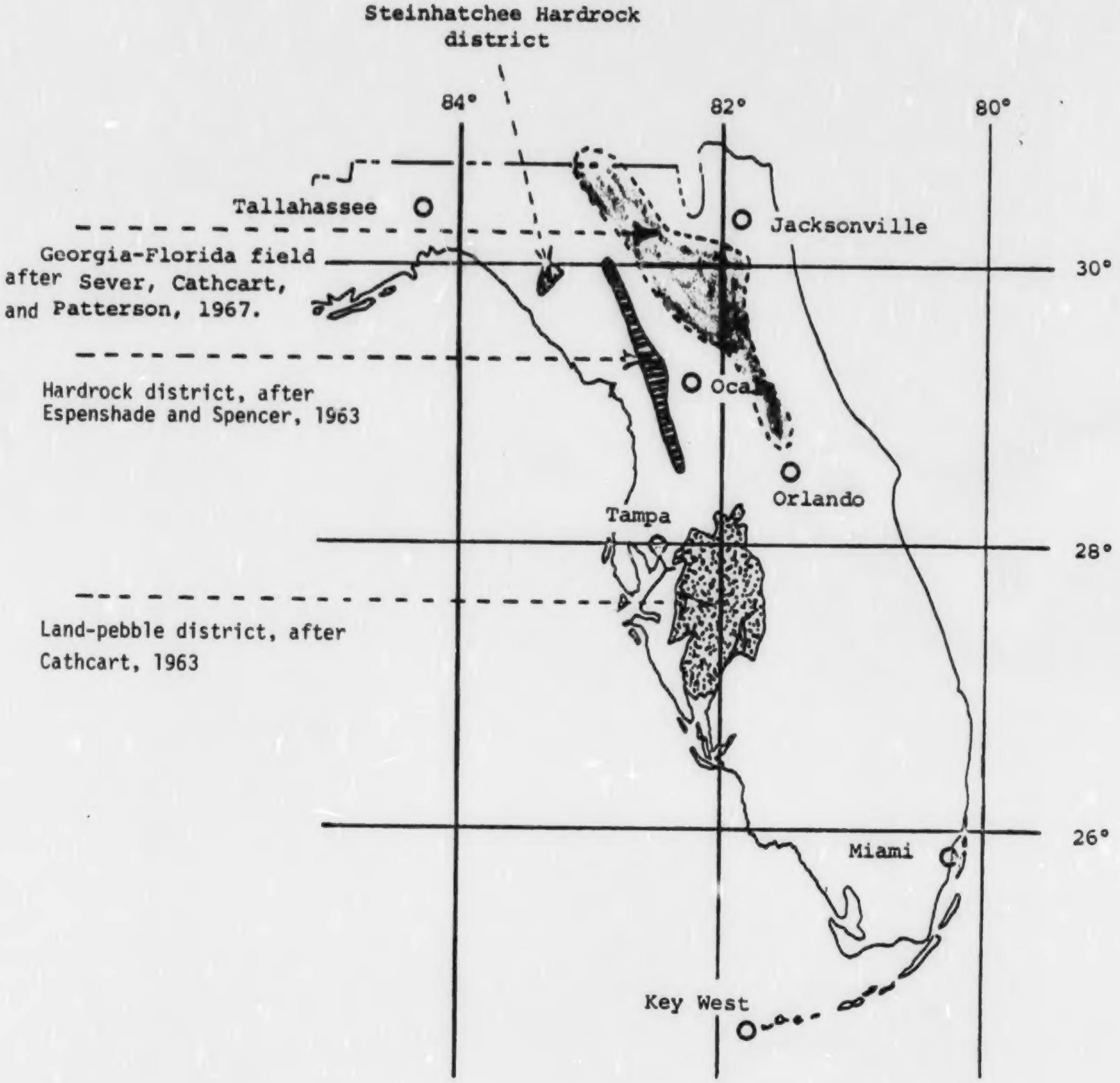

232 90 Th 1.4 x 10^10 yr
228 88 Ra 5.8 yr.
228 89 Ac 6.1 hr.
228 90 Th 1.9 yr.
224 88 Ra 3.6 da.
ATOMIC WGT. ELEMENT
ATOMIC NO.
HALF-LIFE
220 86 Rn 54 sec.
GAS
216 84 Po 0.16 sec.
212 82 Pb 10.6 hr.
212 83 Bi 1 hr.
65%
35%
212 84 Po 3 x 10^-7 sec.
208 81 Tl 3.1 min.
208 82 Pb Stable

Figure 2



Steinhatchee Hardrock district
84°
82°
80°
Tallahassee
Jacksonville
Georgia-Florida field after Sever, Cathcart, and Patterson, 1967.
30°
Hardrock district, after Espenshade and Spencer, 1963
Ocala
Orlando
Tampa
28°
Land-pebble district, after Cathcart, 1963
26°
Miami
Key West

Figure 3. Map of Florida, showing location of phosphate districts.

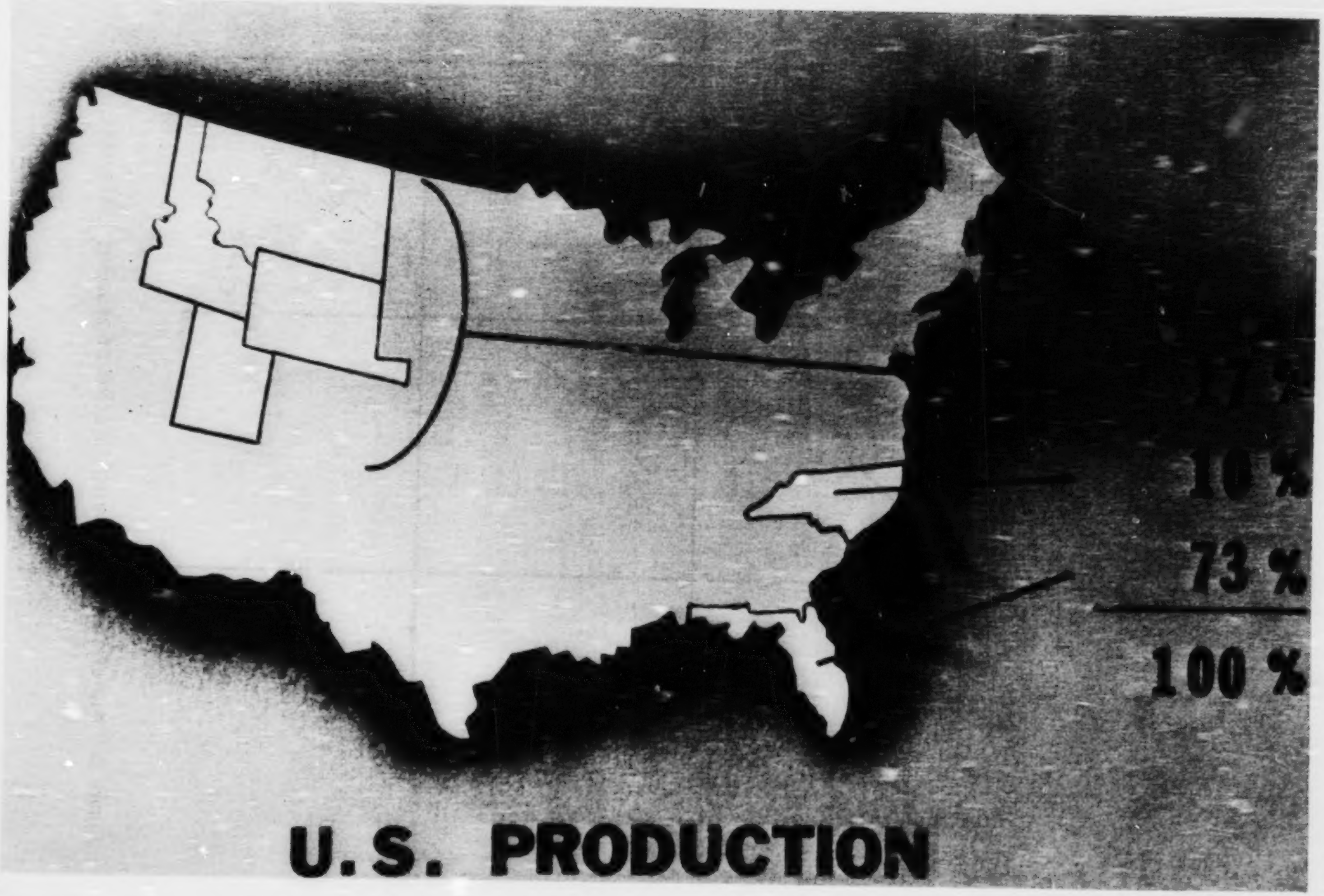

10 %
73 %
100 %
U.S. PRODUCTION

Figure 4. U.S. production of phosphates - Florida Phosphate Council Publication.

The phosphates are distributed in two major types of deposits. Vast quantities of pebble phosphate are found in a relatively small area about 40 miles wide by 50 miles long. This area (about 2000 square miles) encompasses parts of six counties. Mining to date has largely been confined to the northern half of the area. The characteristics of these deposits are, from the surface downward, (a) an overburden or cover of unorganized elastic materials principally sands, ranging in thickness from a few inches to 40 feet in the southern half of the field; (b) below the cover or overburden is found a leached zone, principally aluminum phosphate, apparently remaining from downward movement of the calcium phosphate materials. This "leached zone" has retained much of the original uranium and in many cases contains higher concentrations of uranium than does the underlying calcium phosphate deposit. This leached material is not presently of economic value and is removed in the mining procedure to expose the underlying calcium phosphate deposits which are the object of the mining operation. The leached zone is not present in all locations of the field. The ore body called matrix consists of about one-third phosphate materials, one-third sands and unrecoverable clays, and one-third water (Fig. 5).

A very similar deposit of pebble phosphate is found in north Florida. Only one mining operation is presently being conducted in the "Georgia-Florida" field. These deposits appear to be considerably lower in uranium and associated radium-226. The exact extent of this field is not known but estimates by Cathcart and others indicate that the deposit may extend as far south as the Orlando area. It is uncertain how much of this deposit will be "pebble" and how much will be hardrock.

Hardrock is the second type of phosphate deposit found in Florida. These deposits are contained in limestone matrix. Known hardrock deposits extend in a relatively narrow belt just inland from Florida's west coast for a distance of about 100 miles. The earliest phosphate mining in Florida (1880) was done in these hardrock deposits and until the 1920's this was a very active mining area. At the present time, no known mining is being done in these deposits. Information is very sketchy as to the uranium content of these deposits. Some very preliminary gamma background measurements in old mines indicates elevated gamma levels which would imply the presence of uranium and its daughter radium. Some care must be exercised in this assumption, since Florida is known to have deposits of monazites and other heavy mineral deposits containing high concentrations of thorium. These deposits are known to occur in modern beach lines along Florida's east coast and deposits have been worked in west Florida. Mining is currently being done in St. Johns County in which titanium is being recovered. In this operation, sands rich in zircon are being stockpiled. These sands are rich in thorium and its daughter products. The scope of this discussion precludes any further examination of this source of environmental radiation. One point should be mentioned, however; studies by U.S. ERDA Health and Safety Laboratory in 1974 (4) reports that, in Central Florida, the gamma energy spectrum both indoors and outdoors indicates that the radiation field derives almost entirely from emitters in the uranium series and states this to be the first time they have encountered such a situation in "all of our surveys." Under "normal" conditions the uranium series is stated to contribute 10 to 30 percent of the gamma dose rate. This effect does not necessarily mean that thorium chain emitters are abnormally low in the region but almost certainly indicates that uranium chain emitters are abnormally (compared with average U.S. levels) high.

In assessing the potential for human exposure let us assume a deposit of phosphate matrix at least 2 feet thick containing an average concentration of 33 pCi/gram of material. It can be calculated (5) that the gamma dose rate in air over such a deposit without overburden would be:

$$\text{Dose } (\mu\text{R/hour}) = 2.5\ C_{Ra}\ (\text{pCi/gram})$$

The gamma dose rate in air over such a slab would be 82.5 μR/hour and an emanation rate for radon-222 would be 52.8 pCi/m^2 sec. The relaxation length (the distance required to reduce radon emanation by a factor of e) is approximately 1.5 meters of earth or approximately ten times greater than the thickness required to reduce the gamma exposure rate by the same factor (5). Only 15 cm of earth would therefore reduce the gamma dose rate in air to 30 μR/hour, 30 cm would reduce it to 11.0 μR/hour, and 45 cm (1.5 feet) to 4.0 μR/hour. A similar order of reduction for radon emanation ould require 450 cm (15 feet). This is of importance since the average depth of the overburden in Polk and Hillsborough counties is about 15 feet. It can then be expected that over many ore bodies the emanation rate will be reduced to only 0.368 the emanation rate over bare ore; that is, emanation rates over an ore body as described above with 15 feet of overburden would be 10 pCi/m^2 sec. This would not be land which has been reclaimed but would represent much of the land underlain by pebble phosphate deposits. It should be noted that under these circumstances gamma dose rates would be principally cosmic ray contribution (3.6 μR/hour). Typical ambient background dose rates in Florida are about 5.0 μR/hour (1.4 μR/hour terrestrial contribution) in areas without heavy metals deposits. An assumption that pre-mining gamma background levels in these areas were low appears valid. The assumption applied to radon emanation and consequently radon concentrations in air does not necessarily follow. Based on the foregoing assumptions, the emanation rate over the assumed ore body would be 2.6 pCi/m2 sec. with 15 feet of overburden. Emanation rates over average soils are reported to be 1.0 pCi/m^2 sec. which produces typical values for radon concentration in outside air in the domain of 0.1 to 1.0 pCi/liter of air (6).

The mining operation consists of removing the overburden to expose the ore body. The ore body is then removed and the overburden is replaced. The process results in an inversion of the order of the occurrence of the overburden and/or mixing of the overburden material. One result is to produce a layer of overburden with a higher average radium-226 concentration than that of the original soil and sands. Material from the leach zone in the course of replacement is usually placed at or near the surface resulting in a surface layer of material having a higher radium-226 concentration than the average material it replaces or of the bulk of the fill material below it. The leach zone ranges in thickness from a few inches to 5 feet. The effect of this higher concentration of radium at the surface is more pronounced relating to gamma levels since slabs of gamma emitting material show little increase in gamma levels at thicknesses greater than 2 feet. The effect on radon emanation is not so pronounced since the fractional radon emanation rate versus depth of bare tailings does not approach unity until a depth of 10 feet is reached and falls off rapidly with decreasing depth (Fig. 5) (5).

Larger pebbles constitute about one-third of the total phosphatic material in the matrix, the remainder being fine phosphate clays. In consequence early mining left a great deal of the phosphatic material behind. The distribution of the radioactivity is also a factor. When mining technologies were improved to recover finer phosphatic material, a flotation process was introduced to separate the phosphatic materials from the finer clays. The result was production of large amounts of slimes containing large quantities of water. Typical slimes have been found to contain on the order of 25 pCi/gram radium-226. Water is removed from the material very slowly resulting in large ponded areas of slimes undergoing dewatering. When reclaimed, these ponds represent thick slabs of rather uniform concentration. Cover placed over them is almost always less than 15 feet. Emanation rates over 10 foot slabs of this material would be about 16 pCi/m^2 sec. (Fig. 6).

Standard reclamation practice will thus tend to increase gamma levels more markedly than it does radon emanation rates. Emanation for example over a bare

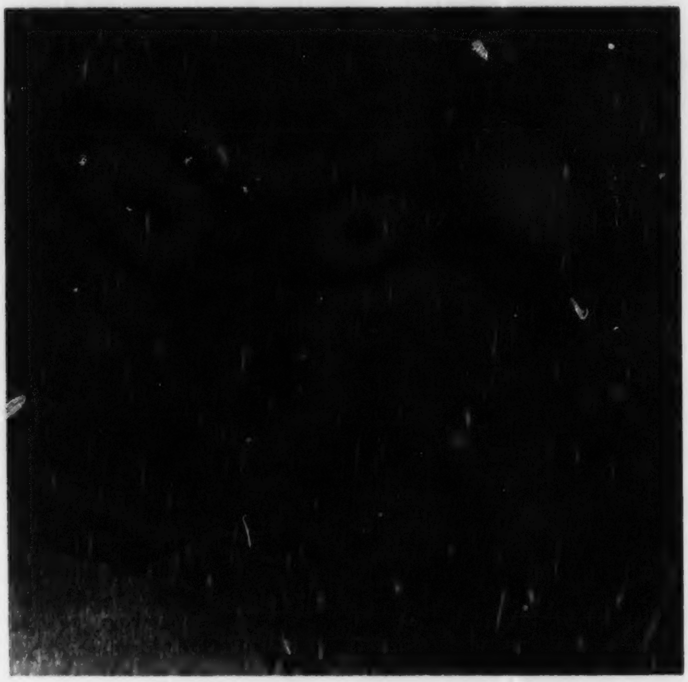


Figure 5. Phosphate mining process - Brewster Phosphate Publication.

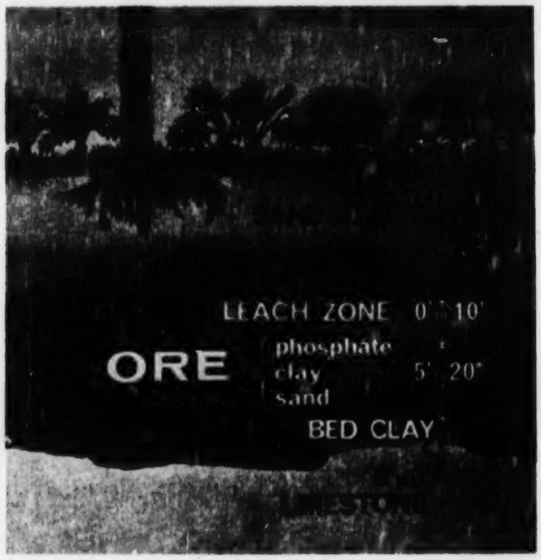

LEACH ZONE 0'-10'
ORE
phosphate
clay 5'-20'
sand
BED CLAY

Figure 6. Schematic view of phosphate deposit - Florida Phosphate Council Publication.

slab of leach zone material 1 foot thick would be (if the concentration were 33 pCi/gram) 31.7 pCi/m^2 sec. If the layer were 6 inches thick this would fall to 15.8 pCi/m^2 sec. It is unlikely that average concentrations of the top foot of the overburden would remain as high as that cited above since mixing with lower concentration material will occur. Table 2 shows radium-226 concentration in various material associated with phosphate mining.

Table 2. Source term - radium-226 (unpublished EPA data)

A.	Matrix	14.0 - 49.0 pCi/gram
B.	Wet Rock	29.1 - 34.0 pCi/gram
C.	Sand (tailings)	6.2 - 8.8 pCi/gram
D.	Slimes	
	Dissolved solids	0.001 - 0.002 pCi/cc
	Undissolved Fraction (clays)	33.5 - 52.0 pCi/gram (2248 pCi/l - 520 pCi/l)
E.	Soils - Control Areas - Florida Division of Health Data	
	Soil	1.5 pCi/gram
	Silt	1.1 pCi/gram
	Beach Sand	0.9 pCi/gram

The foregoing material is not presented in an attempt to be complete or scholarly but to point out some of the parameters that must be considered in any attempt to assess potential Working Level concentration in structures on reclaimed (or other) land before construction. Further complexities are introduced by various combinations of mining practices and reclamation. Early mining was conducted to remove only the larger phosphate pebbles from the matrix. This practice resulted in large quantities of highly phosphatized material remaining whose concentrations of radium-226 are essentially identical to those of the original matrix. In these older minining areas mixing of this highly phosphatized material may result in a more uniform mixture of material containing higher average concentrations of radium-226 than did the original overburden.

Consideration of human exposure to radiation from the above sources has extended over many years. The Florida State Board of Health (now Department of Health and Rehabilitative Services) conducted "measurement of external gamma radiation and radioactivity in air, food, and water" in 1964 (7). The report of this study states "the region encompassed by the Bone Valley phosphate deposit of Central Florida has a significantly higher background radiation level than the remainder of the state."

A study conducted by the U.S. Atomic Energy Commission in 1971(4) states: "The inhomogeneity of the radiation field in this area (Central Florida) renders it difficult to establish any broad generalizations concerning radiation exposure to the local population. Such exposure undoubtedly varies considerably from individual to individual, perhaps covering the entire range of such exposure that might be measured in the continental United States. The population in this area is well in excess of 100,000 people, of whom perhaps as many as 8,000 are employed by the phosphate industry. Considering the levels encountered within the phosphate plant that we surveyed as well as the anomalous home and outdoor environments that seem fairly widespread, it is possible that there may be hundreds of individuals in this region whose radiation exposure approaches or even exceeds 500 mrem/year. It is also quite possible that the mean exposure averaged over the whole population may exceed the national average by something like 50 percent."

In 1973 a report, Reconnaissance Study of Radiochemical Pollution from Phosphate Rock Mining and Milling, was released by the Environmental Protection Agency, National Field Investigations Center, Denver, Colorado (8). The conclusion of this study was: "As a result of reconnaissance studies conducted from August to November 1973, and summarization and interpretation of previous monitoring data, it can be shown that the mining and milling of phosphate rock for phosphorous and phosphatic fertilizers constitutes an important source of radium being discharged to the environment." A recommendation of this study was that: "EPA immediately initiate an investigation to determine the magnitude and effect of radium-226 in seepage of contaminated water from gypsum ponds, etc." and "to ascertain the possible hazard of emissions of radium and its decay products as a result of phosphate manufacturing."

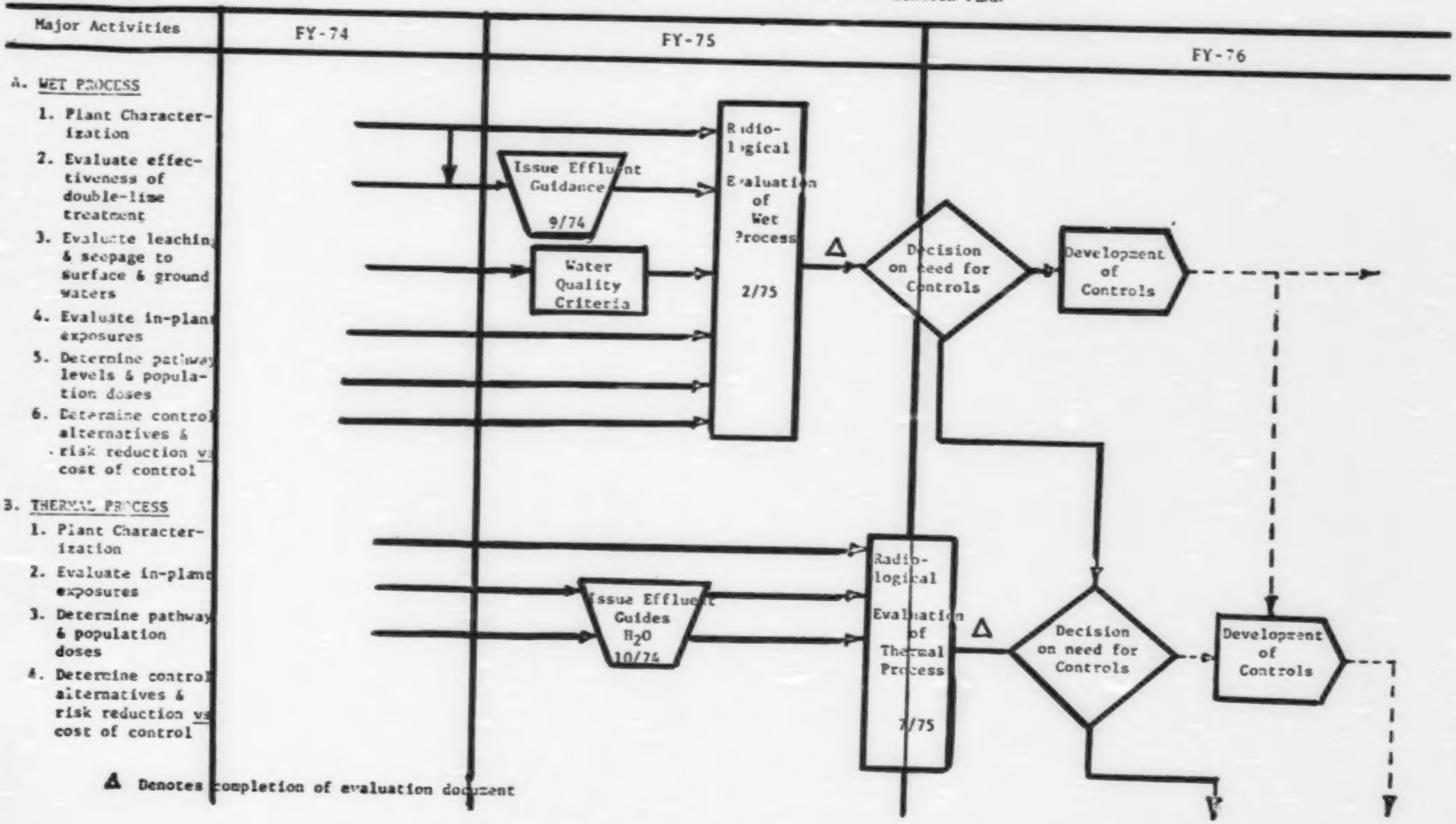
In August 1974, the Criteria and Standards Division, Office of Radiation Programs, Environmental Protection Agency issued "Interim Radium 226 Effluent Guidance for Phosphate Chemicals and Phosphate Fertilizer Manufacturing - Statement of Considerations." This report stated: "We recommend that, on the basis of best practicable technology, the best general interim policy is to include a radium 226 maximum limit of 9.0 pCi/liter in discharge permits." Following this, the Office of Radiation Programs, Environmental Protection Agency issued a "Problem Resolution Plan - Population Exposure from Concentrations of Radioactive Materials in Non-nuclear Industrial Processes, Effluents, Residuals and Products." This document states: "Solution - From the standpoint of the radiation problems associated with these mining and processing industries, the solution is to develop, implement, and enforce public policies to assure that the public and the environment are protected from sources producing effluents, wastes, or commercial products which introduce naturally occurring radioactive material into the surface or near-surface environment. These policies must be promulgated through EPA standards, criteria, or guidelines, and implemented and enforced either by EPA or other Federal Regulatory Agencies, or State and local Agencies." Major steps in this plan are shown in the following chart.

In September 1975, a report was issued by the Office of Radiation Programs, U.S. EPA (11). The report stated: "The data collected over a five-week period suggests that structures build on reclaimed land have radon daughter levels significantly greater than structures not built on reclaimed land. Continuous exposure to the highest level measured (0.2 working level) for ten years may increase the normal risk of lung cancer for an occupant of the structure by a factor of about two. Nevertheless based on these findings consideration should be immediately given to providing the State of Florida with the recommendation that continued use of reclaimed land for new structures construction be discouraged." This report was delivered to the Governor of Florida on October 1, 1975. The impact of the report has been significant. Hillsborough County has placed a moratorium on issuance of building permits for reclaimed land. A similar action was not taken in Polk County, however permit applications are being screened on an individual basis. In Florida a severance tax is imposed on the phosphate mining industry. One function of this law is to return to the payer a percentage of the tax as an incentive for land reclamation. This return is based on determination by the Florida Department of Natural Resources that no significant health or safety hazard exists on reclaimed land. Largely as a result of the above cited report, refunds under this law are currently being held up by the Florida Comptroller pending resolution of the health and safety problem. At last report ten million dollars are impounded.

INGESTION PATHWAY

The problem has not remained confined to the gamma-radon levels in the active mining areas. The Reconnaissance Study (8) previously cited contained

MAJOR STEPS IN THE PHOSPHATE INDUSTRY EVALUATION PLAN


Major Activities
FY-74
FY-75
FY-76
A. WET PROCESS
1. Plant Characterization
2. Evaluate effectiveness of double-lime treatment
3. Evaluate leaching & seepage to surface & ground waters
4. Evaluate in-plant exposures
5. Determine pathway levels & population doses
6. Determine control alternatives & risk reduction vs cost of control
B. THERMAL PROCESS
1. Plant Characterization
2. Evaluate in-plant exposures
3. Determine pathway & population doses
4. Determine control alternatives & risk reduction vs cost of control
Issue Effluent Guidance 9/74
Water Quality Criteria
Radiological Evaluation of Wet Process 2/75
Decision on need for Controls
Development of Controls
Issue Effluent Guides H2O 10/74
Radiological Evaluation of Thermal Process 7/75
Decision on need for Controls
Development of Controls
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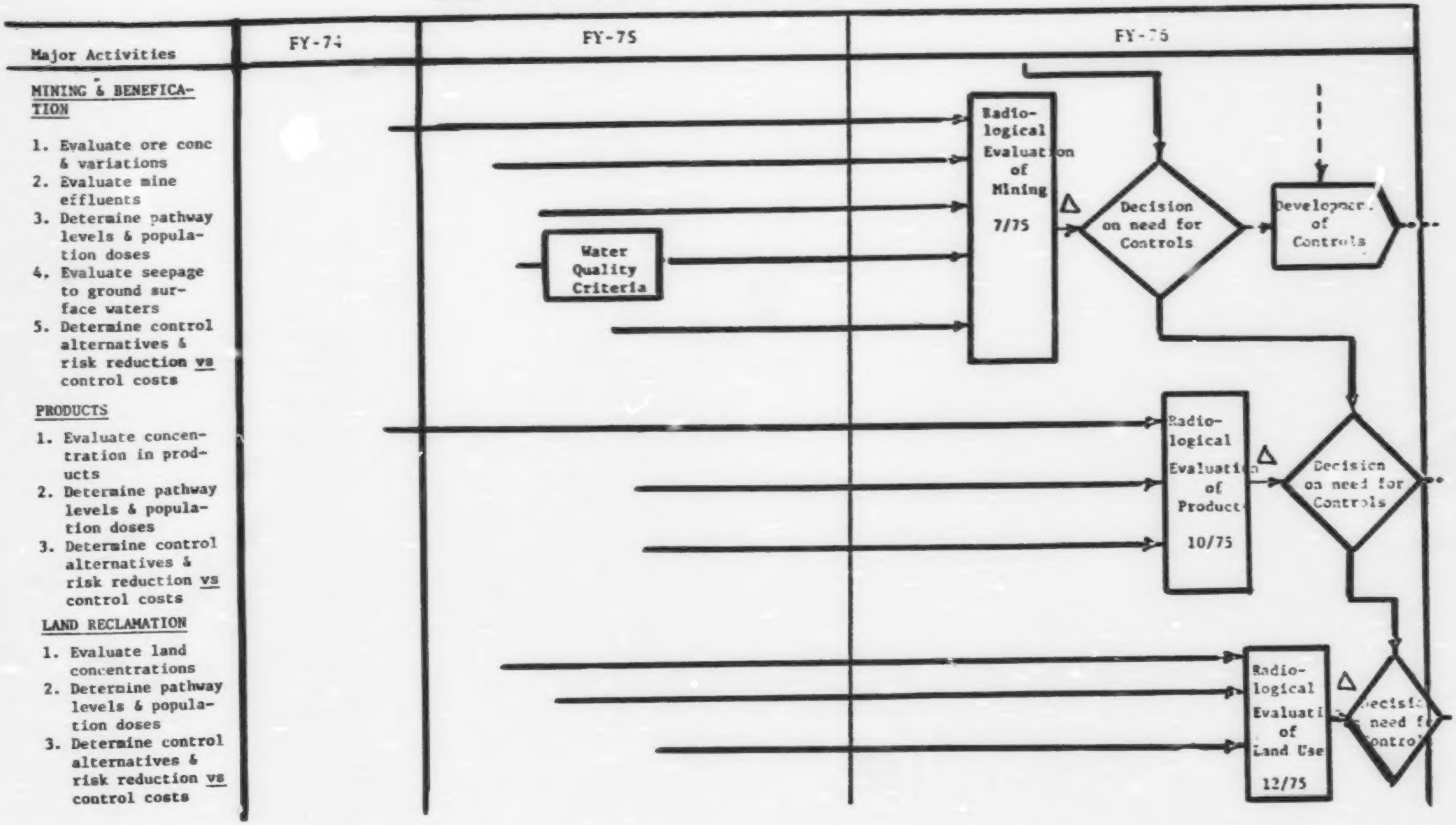
Δ Denotes completion of evaluation document

Continued

MAJOR STEPS IN THE PHOSPHATE INDUSTRY EVALUATION PLAN


Major Activities
FY-74
FY-75
FY-76
MINING & BENEFICATION
1. Evaluate ore conc & variations
2. Evaluate mine effluents
3. Determine pathway levels & population doses
4. Evaluate seepage to ground surface waters
5. Determine control alternatives & risk reduction vs control costs
PRODUCTS
1. Evaluate concentration in products
2. Determine pathway levels & population doses
3. Determine control alternatives & risk reduction vs control costs
LAND RECLAMATION
1. Evaluate land concentrations
2. Determine pathway levels & population doses
3. Determine control alternatives & risk reduction vs control costs
Water Quality Criteria
Radiological Evaluation of Mining 7/75
Δ
Decision on need for Controls
Development of Controls
Radiological Evaluation of Products 10/75
Δ
Decision on need for Controls
Radiological Evaluation of Land Use 12/75
Δ
Decision on need for Controls

results of radium-226 and radon-222 concentrations in Central Florida Ground Waters. This report of sampling conducted in January 1966 included:

25	Municipal Supplies (Well)
80	Privately Owned Wells
1	Thermal Spring
1	Natural Well
2	River Water Samples
2	Industrial Waste Samples

The results of these analyses were (8):

	Radon-222	Radon-226
105 Drilled Wells	23 - 46,600 pCi/l	0.0 - 76.0 pCi/l
80 Private Wells	23 - 46,600 pCi/l	0.0 - 76.0 pCi/l
25 Municipal Wells	35.0 - 720.0 pCi/l	0.0 - 4.1 pCi/l

The State's Orlando Radiological Laboratory does not presently have the capability for radium-226 analysis in drinking water by "Standard Methods" procedures. Radium-226 analysis in this laboratory is confined to gamma spectroscopy methods in which the Minimum Detectable Levels are too high to be of value in analysis of drinking water. Historically, the only drinking water supplies which have been analyzed in Florida have been Interstate Common Carrier watering points with analysis for gross alpha activity only. No samples under that limited program have been submitted since January 1972, perhaps as a result of extensive reorganization of the State agencies involved. Partially as a result of the Reconnaissance Study, samples were collected by the Florida Radiological Health Program in conjunction with County Health Units for radiological analysis for gross alpha activity.

To date analyses for radioactivity in fresh water have been conducted on a total of 420 water supplies. A total of 210 samples have been analyzed for specific radium-226 concentration, principally by the U.S. EPA Eastern Environmental Radiation Facility in Montgomery, Alabama. These samples (radium-226) are largely contained in the number reported for gross alpha analysis and represent samples determined to contain concentration of gross alpha activity greater than 2.0 picocuries per liter. These analyses do not detect radon-222 or the beta particle emitting radium-228 (Figs. 1 and 2).

Criteria utilized for evaluating these analyses are those proposed by the U.S. Environmental Protection Agency (FEDERAL REGISTER, August 4, 1975). These criteria for natural radioactivity are as follows:

A. If gross alpha >2 pCi/l, radium 226 analysis required.

B. If radium-226 >3 pCi/l, analysis for radium-228 required.

C. Combined radium may not exceed 5 pCi/l.

D. Gross alpha particle radioactivity may not exceed 15 pCi/l.

Results of samples to date are shown in Table 3. Based on these data, the following conclusions can be drawn:

1. Of 420 samples screened by gross alpha analysis, 68 percent require further analysis for radium-226.

2. Of 420 samples, 110 (26 percent) exceed the EPA criteria limit for gross alpha activity (15.0 pCi/l).

3. Of 210 samples analyzed for radium-226, 61 (29 percent) require additional analysis for radium-228.

Table 3. Natural Radioactivity in Florida Wells

Florida Water Samples Evaluated by Gross Alpha Analysis

County	Wells Sampled	Number >2	Number >15
Columbia - Hamilton	31	17	2
Sarasota	72	64	62
Manatee	64	44	19[a]
Hillsborough	50	35	5
Polk	50	40	1
Orange	50	22	2
U.S. EPA (Interstate Carrier Program- 29 in Polk County)	34	11	0
U.S. EPA Reconnaissance Study (8)	33	23	6
Samples connected with CFI Sinkhole	36	29	13
TOTAL	420	285	110

Results Radium-226 Analysis in Drinking Water

	Samples	>3.0 pCi/1	Percent
Polk County [b]	116	25	21
Manatee County [c]	22	7	32
Sarasota County [c]	33	22	67
Non-classified counties [d]	39	7	18
TOTAL	210	61	29

[a] Gross alpha not reported if analysis exceeded 2.0 pCi/l. Number radium-226 >3.0 pCi/l - 7. For those samples on which gross alpha only was done the number > 16.0 pCi/l was 3.

[b] 50 samples analyzed by University of Florida Environmental Engineering Laboratory. Remainder by EPA-EERF.

[c] All analyses by EPA Eastern Environmental Radiation Facility.

[d] Samples analyzed by U.S. Geological Survey-Denver for Florida DER.

It will ultimately be required that all public water supplies in Florida be monitored for radioactivity to meet Federal standards outlined in Public Law 93-523 Safe Drinking Water Act. In the meantime, it is our feeling that analyses should be done on samples from counties approximating in area the pebble phosphate deposits of Central Florida. These counties will include Polk, Hillsborough, Manatee, Sarasota, Hardee, Desoto, and Glades. To date, analyses have been conducted from the first four counties.

Analyses of samples from Sarasota County show a strong correlation with total solids of sample. This effect may be linked to salt water intrusion which has been experienced in the area. Based on this finding, it is our feeling that immediate sampling should be conducted in Charlotte, Pasco, and Lee Counties.

In addition sampling in Orange County (used as a control for Polk) indicates elevated gross alpha levels in the western third of the county. It is therefore recommended that sampling be conducted in Orange and Lake Counties.

Estimates of the number of public water supplies in the above areas are shown below.

County	Number Public Water Supplies[a]
Hillsborough	400
Polk[b]	475
Manatee[b]	16
Sarasota[b]	365
Charlotte	21
Lee	200
Hardee	100
DeSoto	100
Orange[b]	1000
Lake	100
TOTAL	2777[a]

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[a] Best estimate by County personnel handling program.

[b] County in which water greater than 3.0 pCi/liter radium-226 has been detected.

EXTERNAL EXPOSURE PATHWAY

To date, we have evaluated the data on ambient gamma radiation levels in structures located in Polk and Orange Counties. Of these structures, 190 were public schools in the counties. The remainder were residences. Two types of measurements are included in the sample.

(1) Measurements made with Ludlum scintillation survey meters are "grab samples" indicating an instantaneous level. A portion of these data were obtained by U.S. EPA personnel during the deployment of TrackEtch Radon Daughter Dosimeters. All of the measurements in the 190 schools were made by Florida HRS personnel. All Ludlum survey meter results here reported have been corrected to reflect the different response of these instruments to distributed sources when they are calibrated against a point source. Calibration of Florida HRS meters has been confirmed by the University of Florida Department of Environmental Engineering (Drs. Bolch and Roessler). The Ludlum scintillation meters are calibrated against a Reuter-Stokes Pressurized Ion Chamber utilized as a secondary standard. Accuracy of this instrument has also been confirmed by the University of Florida group mentioned above. The series of Ludlum measurements in Polk County residences were made with selection of structures based on their status as to location on reclaimed or unreclaimed land. The 190 measurements in schools were not site selected in this regard.

(2) The second type of measurement involved Thermoluminescent Dosimeters (caF:Mn). These were deployed for a 60-day period, and thus constitute an integrated sample. The dosimeter utilized consisted of two CaF:Mn chips

enclosed in an energy compensating shield and mounted in a plastic holder. Two such packages (4 CaF:Mn) chips were deployed in each residence, one in a sleeping area and one in a living area. No attempt was made to maximize the reading, and instantaneous measurement was not made. These dosimeters were calibrated by Florida HRS personnel against a cesium-137 source. These dosimeters were also compared in the field against glass enclosed CaF:Mn dosimeters used in our reactor surveillance program. The glass bulb dosimeters are also deployed in an energy compensating shield. This intercomparison provided a correction factor which has been applied to the TLD results previously reported.

Results are shown in tables 4A and 4B. The divisions shown for Polk County are somewhat arbitrary. The north-south dividing line is State Road 60. The east-west dividing line follows a perpendicular dropped along the east side of Range 26 east.

Table 4A. Evaluation of Gamma Backgrounds - Polk County

Residences: County $\bar{X}$ 9.36 R 5.9 - 31.0 σ 3.28 N 229

	Southeast	Southwest	Northeast	Northwest
$\bar{X}$	12.08	10.9	8.75	8.75
R	6.9 - 31.0	6.8 - 18.8	5.9 - 18.1	5.9 - 15.7
σ	8.19	3.23	3.53	2.26
N	12	50	13	154

Schools (89)

	East	Southwest	North Central	West
$\bar{X}$	7.9	9.34	7.5	8.5
R	6.3 - 11.2	6.3 - 12.5	6.3 - 9.6	6.3 - 16.3

Table 4B. Evaluation of gamma backgrounds - Orange County
(high inside gamma)

Residences: County $\bar{X}$ 7.3 R 5.2 - 43.3 N 49

	Southeast	Southwest	Northeast	Northwest
$\bar{X}$	7.2	6.5	11.5	10.1
R	5.6 - 16.1	5.8 - 7.1	6.0 - 21.5	5.2 - 43.3
σ	1.09	0.5	6.0	11.7
N	27	4	8	10

Schools (mean inside gamma)

	Southeast	Southwest	Northeast	Northwest
$\bar{X}$	7.6	7.3	7.1	7.4
R	5.8 - 15.3	6.2 - 13.2	5.9 - 9.3	6.0 - 22.3
σ	1.87	1.56	0.99	2.75
N	26	22	15	34

Table 5 contains results of measurements with the Reuter-Stokes pressurized ion chamber at 67 randomly selected locations in Polk County. These measurements were made over a variety of land type; i.e., reclaimed, undisturbed, old mining, and so forth. It can be seen that the highest single measurement was obtained at Mary Holland Park in Bartow, which is known reclaimed land. It is of interest to note that measurements made at the Hancock Mine which was in the process of reclamation were on the order of one-half as high. The range of all readings was 5.0 to 45.0 μR/hour.

A further area of interest in the gamma results lies in the reduction in gamma levels. An evaluation of measurements made at 161 locations indicate that this reduction ranges from 4.3 to 39.3 percent. The greater precentage reductions occur when outside gamma levels are higher (Fig. 7).

Based on the gamma data reported above, the Florida Department of Health and Rehabilitative Services has concluded that no substantial gamma background problem has been demonstrated. State effort is being channeled therefore into a supplemental screening study for radon daughters in structures. The study is modeled on that conducted by U.S. EPA and will utilize deployment of Alpha Track Etch Film for monitoring Working Level into 1000 structures.

This film will be furnished by the General Electric Company Vallecitos Nuclear Center. The dosimeters will be deployed for 12 months. Upon completion of this period, the badges will be returned to the General Electric Company for processing which will involve dipping the badges in a caustic solution (NaOH) which will etch the record of alpha passage in the film. Each badge after etching is read by a technician using a light microscope with a calibrated field. The number of tracks per square millimeter is determined. Working Level hour values can be calculated from track density measurements. This value divided by the hours of exposure will give the average concentration in Working Level. The calculation used will be based on experimental work in Grand Junction, Colorado. The accuracy of the measurement is strongly dependent on total working level hours of exposure. The expected error for the 6- and 12-month deployment is calculated to be:

Working Level	12-Month deployment (percent error)	6-Month deployment (percent error)
.001	165	224
.002	121	165
.005	80	109
.01	59	80
.02	43	59
.05	29	39
.1	21	29
.2	16	21
.5	10	14
1.0	8	10

Because of the increased error with lower total working level hours, the decision has been made to made no deployment of badges for collection after 6 months. Preliminary results by U.S. EPA(11) range from 0.0002 WL to 0.2013 WL, indicating an expected range of error from an estimated ±200 percent to ±43 percent. Twenty percent (200) of the 1000 structures will have two films deployed for the entire period providing duplicate determinations.

In addition to the above measurements, an additional 200 structures will have measurements of Working Level made utilizing the air sampling system as used by the Environmental Protection Agency developed by Colorado State Univer-

Table 5. Ambient Gamma Background at 3 Feet (Measured with Pressurized Ion Chamber - Reuter-Stokes)

Location		µR/Hour
S31 T31S R26E		20.0
S32 T31S R26E		15.0
N ¼ Sec. 1-6 T32S R26E		15.0
S36 T31S R25E	Trailer Park	7.0-10.0
S19 T28S R23E		8.0
S16 T27S R23E	Kathleen	6.3
S17 T27S R23E	Kathleen	6.5
NE ¼ S 20 T27S R23E	Kathleen	8.0
SE corner S17 T27S R23E	Paved Road	21.7
S17 T27S R23E		8.0
S5 R23E T27S	Socrum	7.0
S4 R23E T27S	Socrum	7.5
S5 R23E T27S	Paved Road	7.0
S5 R23E T27S	Off Paved Road	7.0
SE R23E T27S	Trailer Park	8.0-10.0
S17 R23E T27S	Rolling Hills Subdivision	6.7
S17 R23E T27S	Rolling Hills Subdivision	6.5
S19 T27S R23E	Trailer Park	6.8
S33 T27S R23E	Subdivision w of Galloway	6.7
S33 T27S R23E	Subdivision w of Galloway	6.0
S32 T27S R23E	Orange Grove next to subdivision	5.7
S33 T27S R23E	Chart Prine Road	35.5
S28 T27S R23E	½ mile N. Galloway	8.0
S28 T27S R23E	½ mile N. Galloway	6.0
S15 T28S R23E	Dirt Road	32.0
S20 T28S R26E	Parking Lot, Polk CHD, Winter Haven	7.5
S8 T30S R25E	Pearl Street, Bartow	28.0
S8 T30S R25E	Parking Lot off Pearl Street	10.0
S8 T30S R25E	Broadway St., Bartow	11.8
S8 T30S R25E	Vacant Lot off Broadway	11.0
S8 T30S R25E	Hooker St., Bartow	20.0
S8 T30S R25E	Vacant Lot off Hooker Street	10.0
S18 T30S R25E Reclaimed	Mary Holland Park, Bartow	45.0
" " " "	" " " " "	39.0
" " " "	" " " " "	39.0
S17 T30S R25E	Subdivision South Bartow	9.0
S18 T30S R25E	" " " " "	10.0
	Day's Inn, Plant City	8.0
S23 T29S R25E	Civil Defense Shop Bartow Airport	7.0
S23 T29S R25E	Paved Road at above	7.0
S11 T29S R25E	Field	5.7
S11 T29S R25E	Paved Road	7.0
S11 T29S R25E	Subdivision	5.7
S22 T29S R25E	Populated Area	6.5
SW ¼ S22 T29S R25E	Old Mined Area	12.0
" " " "	" " "	31.0
" " " "	" " "	24.0
" " " "	" " "	38.0
S34 T26E R31S	Orange Grove	6.0
S2 T32S R28E	McGrady's Trailer Park	5.0
S6 T32S R23E	Robert's Trailer Park	5.0
S10 T31S R27E	KOA Camp	5.3
S29 T30S R28E	Sandy Cove Trailer Park	6.3
S26 T30S R27E	Campin Aires Campe	6.0

S14 T30S R27E	Lake Wales Motel	5.5
S18 T28S R25E	Beasley's Trailer Park	5.3
	Gibsonia Trailer Park	6.0
SE Corner S21 T27S R23E	1 mile N. Galloway	6.3
SE Corner S26 T27S R23E	Town of Galloway	13.0
S28 T27S R23E	Young's Ridge Trailer Park	7.0
S4 T30S R25E	Peace River Village Trailer Park	8.0
S16 T29S R25E	Hancock Mine Slime Pit	21.0
S10 T29S R25E	Hancock Mine Overburden	12.0
S10 T29S R25E	Hancock Mine Tailings	22.0
S10 T29S R25E	Hancock Mine Sandpile	23.0
S10 T29S R25E	Hancock Mine Dike	17.0

Table 6. High Outside Gamma vs. High Inside Gamma - Polk County
County at Large

High Outside Gamma			High Inside Gamma
N = 161 $\bar{X}$ = 14.52 μR/Hr σ 7.28 Range 5.9 - 44.3 μR/Hr		= 37.6%	N = 161 $\bar{X}$ = 9.05 μR/Hr σ 2.67 Range 5.9 - 18.8 μR/Hr
Southeast			
N = 1	HOG = 10.1 μR/Hr	= 8.9%	HIG = 9.2 μR/Hr
Northeast			
N = 3	$\bar{X}$ = 6.17 μR/Hr σ = .23 Range 5.9 - 6.3 μR/Hr	= 4.3%	$\bar{X}$ = 5.9 μR/Hr σ = 0 Range 5.9 μR/Hr
Southwest			
N = 31 N = 31	$\bar{X}$ = 15.92 μR/Hr σ = 8.13 Range 8.2 - 35.3 μR/Hr	= 33.6%	$\bar{X}$ = 10.57 μR/Hr σ = 3.34 Range 6.8 - 18.8 μR/Hr
Northwest			
N = 126	$\bar{X}$ = 14.41 μR/Hr σ = 7.04 Range 6.3 - 44.3 μR/Hr	= 39.3%	$\bar{X}$ = 8.75 μR/Hr σ = 2.36 Range 5.9 - 13.9 μR/Hr

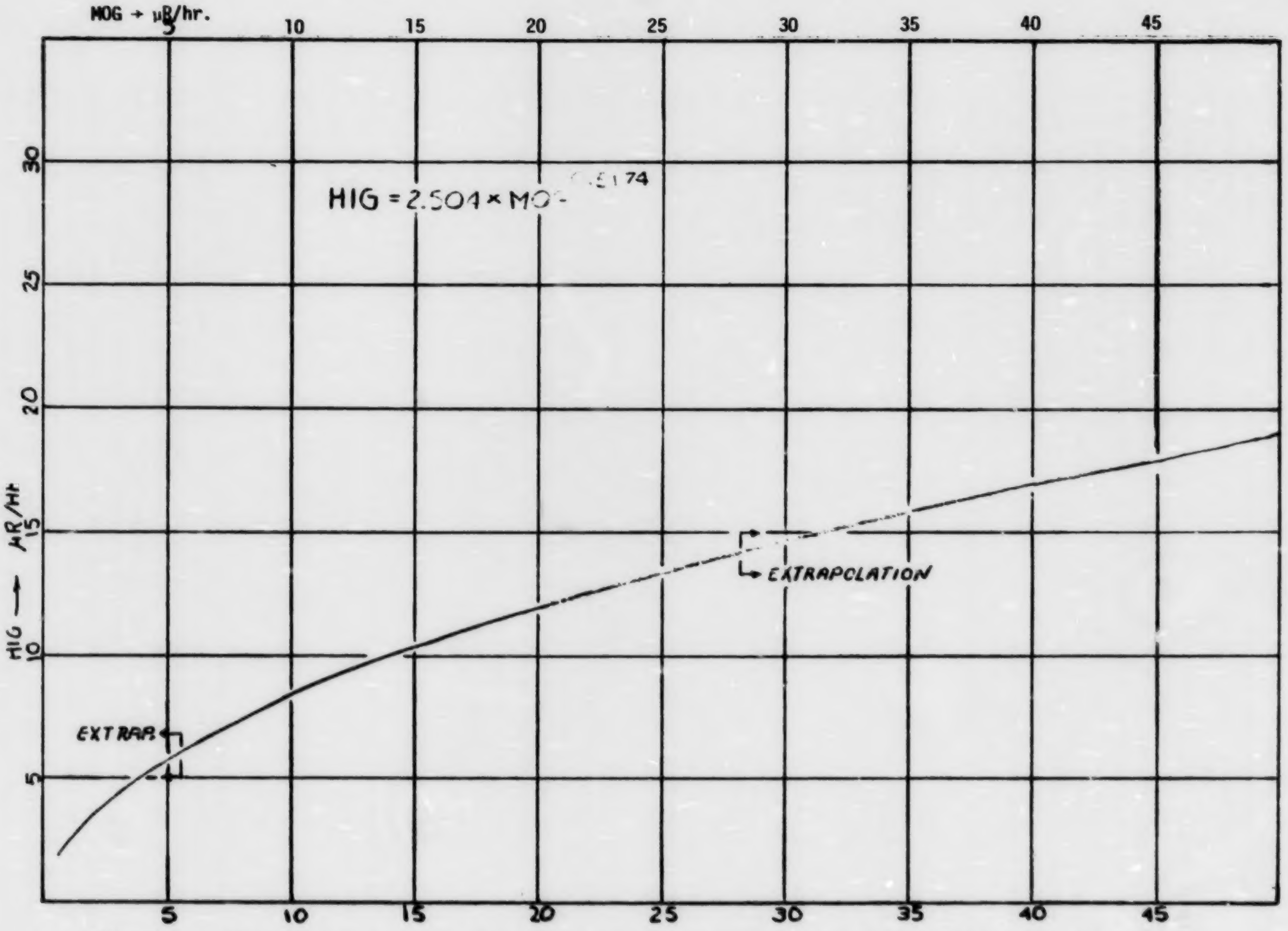

Figure 7. Plot of average outside gamma levels versus high inside gamma levels in Polk County structures.

sity, Fort Collins, Colorado and known as the Radon Progeny Integrating Unit. This unit utilizes the detection techniques of thermoluminescent dosimetry. The State is currently constructing 10 of these devices. At least four measurements will be made over a 1-week period each time with selected weeks distributed approximately equally over the year. Calibration of the TLD's will be done by U.S. ERDA Health and Safety Laboratory in New York. Reading of the dosimeters will be done either by U.S. EPA or by State personnel utilizing a Victoreen Model 2800 TLD Reader. Values obtained, in Working Level, will be utilized as a more immediate estimate of Working Level as well as a cross check against the Track Etch Dosimeters. At the time of deployment of the track etch dosimeters, a mapping of ambient gamma levels inside and outside the structures will be made utilizing scintillation detectors (Ludlum Instrument Company Model No. 12S Micro R Meter with a counting range of 0 to 30 micro R/hour with multiples of x 0.1, x 1, x 10, and x 100). These gamma measurements will be verified by use of a Reuter Stokes Pressurized Ion Chamber (Model RSS-111 Environmental Radiation Monitor).

One major drawback of using the track etch dosimeters lies in the fact that a full 12-month deployment period must be used. We are advised by General Electric Company that reading of the 1200 dosimeters will require up to 60 days. As a consequence no useful data will be obtained in less than 14 months from the date of deployment. Furthermore, these dosimeters will be used only in existing structures. A major area of concern therefore is how to make measurements on unimproved land with the goal of predicting radon daughter concentrations (WL) in hypothetical structures to be built thereon. This presents a major technical challenge since radon concentrations in air vary widely over the course of a day and are extremely sensitive to meterological conditions. In studies conducted by U.S. ERDA Health and Safety Laboratory at Lloyd, New York, continuous monitoring was conducted during the period September 27 - October 24, 1975. Daily average radon concentration varied from 25 to 190 pCi/m^3 with a mean value of 105 pCi/m^3.

These values in a carefully controlled field study indicate that daily ranges may be on the order of 4 or 5, while seasonal average variation may be on the order of a factor of 2. In comparison, values reported in a series of measurements made in Bartow in Polk County during 1964-1965 indicated an average daily range of 42 to 276 pCi/m^3 from July 1963 to August 1964. The maximum of the means during the period April 1964 - Febraury 1965 in Bartow ranged from 400 to 1163 pCi/m^3. Maximum recorded values by month during the period ranged from 1500 to 3125 pCi/m^3 (7) (Fig. 8).

On February 23, 1976, in a letter from U.S. Environmental Protection Agency to the Administrator of the Radiological and Occupational Health Section, Florida Department of Health & Rehabilitative Services, we were advised that some minor changes in the overall levels reported for specific structures has occurred. As a result the highest structure previously reported as 0.2 WL (based on two observations) is now reported to be 0.105 WL (based on four observations). The original range of WL concentrations reported by U.S. EPA was 0.0002 WL to 0.205 WL (11). This is now reported to be 0.0002 WL to 0.105 WL.

Additional measurements are being made by U.S. EPA at this time. Measurements by State personnel are being made to determine concurrent inside-outside WL concentrations in selected structures. There is a scarcity of data relating to outside WL concentrations. Difficulties that have been encountered relate to problems of measurement of WL concentrations. All existing measuring systems are adversely affected by dust loadings, since the Radon Progeny Integrating Sampling Unit uses a filter system as does the Instant Working Level Meter developed by Kerr-McGee, Inc. and produced under license by MDA Scientific Inc. of Park Ridge, Illinois (13). A strip mining region may be expected to have reasonably heavy dust loadings at certain times. Efforts to bypass the dust loading problem are being made by using Lucas Scintillation Cells to measure

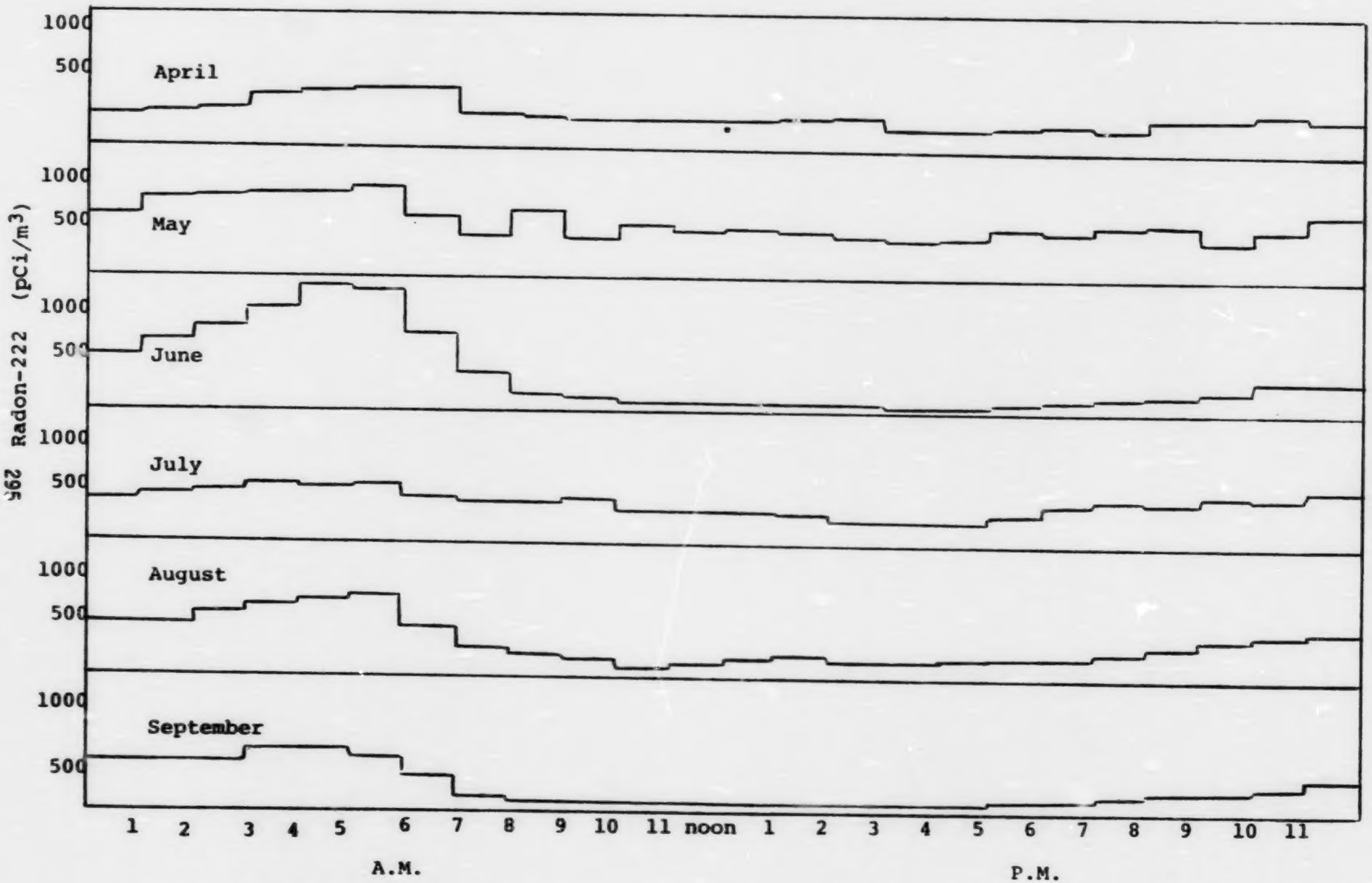

Figure 8. Average monthly radon-222 diurnal variations - Bartow - April 1964-September 1964.

radon-222 concentrations rather than WL concentrations. This permits use of a prefilter to remove dust. Problems are expected with this technique at low concentrations. It may be necessary to use some kind of cryogenic concentration techniques or to use scintillation chambers with volumes greater than 100 ml.

The greatest problem at this time relates to establishment of suitable guidelines for acceptable exposures. On January 22, 1976, in a letter to the Director, Division of Health, U.S. EPA issued the following: Interim Recommendations for Gamma Exposure Levels at New Structures Sites on Florida Phosphate Lands.

External Gamma Radiation Level	Recommendation
Equal or greater than 0.01 mR/hr	Construction should be delayed pending additional study or acceptable control technology should be instituted to preclude indoor radon daughter problems.
Less than 0.01 mR/hr	Construction may be initiated.

These criteria do not define the "radon daughter problems" which the control technology suggested is to preclude. The only guidelines available at this time for non-occupational exposure are those promulgated by the Surgeon General in July 1970 to apply specifically to dwellings constructed with or on uranium mill tailings (11).

Indoor Radon Duaghter Products

Level	Recommendation
Greater than 0.05 WL	Remedial action indicated
From 0.01 to 0.05 WL	Remedial action may be suggested
Less than 0.01 WL	No action indicated

These levels constitute exposures which are in addition to the natural background levels found within dwellings in the area not constructed on or with uranium mill tailings (in Grand Junction, Colorado, approximately 0.004 WL).

This lack of guidance on acceptable concentrations of WL in non-occupational exposure makes use of any land in Florida having a gamma level greater than 0.01 mR/hr impossible until such guidance is forthcoming.

In a recent series of measurements of ambient gamma levels at the Central Florida Junior College in Ocala, Marion County levels of 0.009 to 0.026 mR/hr were demonstrated with a mean value of 0.011 to 0.012 mR/hr. This location is some 100 miles north of the pebble phosphate fields of Polk and Hillsborough Counties and has no relationship to phosphate mining activity. The activity is apparently related to the Hawthorne formation and may indicate that large areas of Florida will exceed the present EPA guideline of 0.01 mR/hr for ambient gamma levels above which construction should be delayed.

Conclusions which may be drawn, as relates to State programs, are:

1. Ambient gamma background levels measured in the phosphate region are not sufficiently high as to indicate a need for control measures.

2. There does not appear, at this time, to be a usable correlation between ambient gamma levels and ambient WL concentrations.

3. It appears necessary that ambient average WL concentrations will need to be determined at every location where ambient gamma levels exceed 0.01 mR/hr.

4. The most critical need is for development by U.S. EPA of allowable concentrations (WL) in the non-occupational situation.

5. Instrumentation and techniques need to be developed to:

a. Make rapid measurement of WL concentration on both an instantaneous and integrated basis.

b. Make rapid measurements of radium-226 concentrations in soil.

6. A model is badly needed which can be used to predict, from measurements of WL concentration on unimproved land, the WL concentration which will exist in structures constructed on the land.

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DISCUSSION

MR. LITTLE (BRH): I was wondering what standard you plan to use with respect to those houses that may have high occupational levels? There was some mention of the Surgeon General's Guidelines; was this to be used or is this some that will follow the revised guidance by EPA?

MR. JOHNSON: We have used the Surgeon General's guidelines as a guide. Unfortunately, these were rather specifically, and so stated, applicable to uranium mill tailings and the Colorado situation. We are a little reluctant to use these now because we are awaiting guidance from EPA and personally I feel that this guidance may give us some lower numbers.

THE NEED FOR RADIATION CONTROLS IN THE PHOSPHATE AND RELATED INDUSTRIES

Gary F. *Boothe*
Division of Environment
Idaho Department of Health and Welfare

Since February 1975, the Radiation Control Section of the Idaho Department of Health and Welfare has been accumulating and reviewing environmental radiation surveillance data related to phosphate industry activities in Idaho. The Radiation Control Section has also been cooperating with the U.S. Environmental Protection Agency in conducting radiation studies in some of Idaho's phosphate plants. The preliminary data from these studies indicate there is a need to impose radiation controls on certain aspects of the phosphate and related industries. The need for controls is immediate in some areas and in some areas more data is needed to form a basis for initiating and implementing other appropriate controls.

The purpose of this report is to explain why controls are needed in Idaho's phosphate and related industries and to discuss what these controls might be.

There are radiological aspects to the phosphate industry because uranium and the uranium daughters occur as trace elements in phosphate ore. In 1973, the U.S. phosphate industries extracted 17,000 tons of uranium oxide while the entire uranium mining industry extracted only 14,000 tons of uranium oxide during the same period *(1)*. In Idaho in 1975, six million tons of phosphate ore were mined *(2)*. Based on the uranium content of the ore, this means that 500 tons of uranium were extracted in Idaho in this one year.

The trace quantities of uranium, radium, and other daughters in phosphate ore are carried over and sometimes concentrated in phosphate products and byproducts. The areas of concern because of these trace quantities of radioactivity include mining, radioactivity in products, radioactivity in processing plants, and the use of radioactive byproducts.

In the area of mining, the specific concerns are occupational radiation exposures to miners and the use of reclaimed mining land. The increased incidence of lung cancer in uranium miners *(3)*, and fluorospar miners *(4)* due to radon daughter concentrations in underground mines has been documented. In the past, there have been underground phosphate mines in Idaho, and this type of mining operation is possible in the future. The radiological problems with the use of reclaimed phosphate mining land have come to light recently in Florida *(5)*. The problems here have been the buildup of radon daughters in houses constructed over exposed soils and deposits containing radium.

The overall radiological impact of radioactivity in phosphate products, such as fertilizers, is apparently not well known, but studies in this area are being conducted by the EPA *(6)*.

The more immediate concerns to the State of Idaho are in the areas of processing plants and the use of radioactive byproducts from these plants. These concerns are augmented by the fact that the Interagency Task Force on the Development of Phosphate Resources in Southeast Idaho estimates that 35 percent of the U.S. phosphate reserves are in Idaho, and that phosphate mining and processing activities will almost triple in Idaho by 1980.

There are two basic types of phosphate processing plants: the wet process plant and the thermal process plant.

Figure 1 depicts the operation of a wet process plant and the radioactive pathways to the environment. Ore is obtained from open pit mines in Idaho; the ore is beneficiated by crushing, scrubbing, and drying and it is then calcined at 1500° F to burn out the organics. Since polonium is a volatile element, polonium-210, a daughter in the uranium decay series, is driven off in the calcination process. Other uranium daughters may also be driven off, since elevated concentrations of radium-226 and thorium-230 have been measured near calciners. The commercial products from wet process plants are phosphoric acid and various fertilizers. Radioactivity may enter the food chain through the use of these products containing trace quantities of radioactive materials. The main industrial byproduct is gypsum, which contains radium--a source of gamma radiation and a potentially leachable contaminate to subsurface waters. In one of Idaho's wet process plants about 1.25 x 10^6 tons of gypsum is produced and piled up each year.

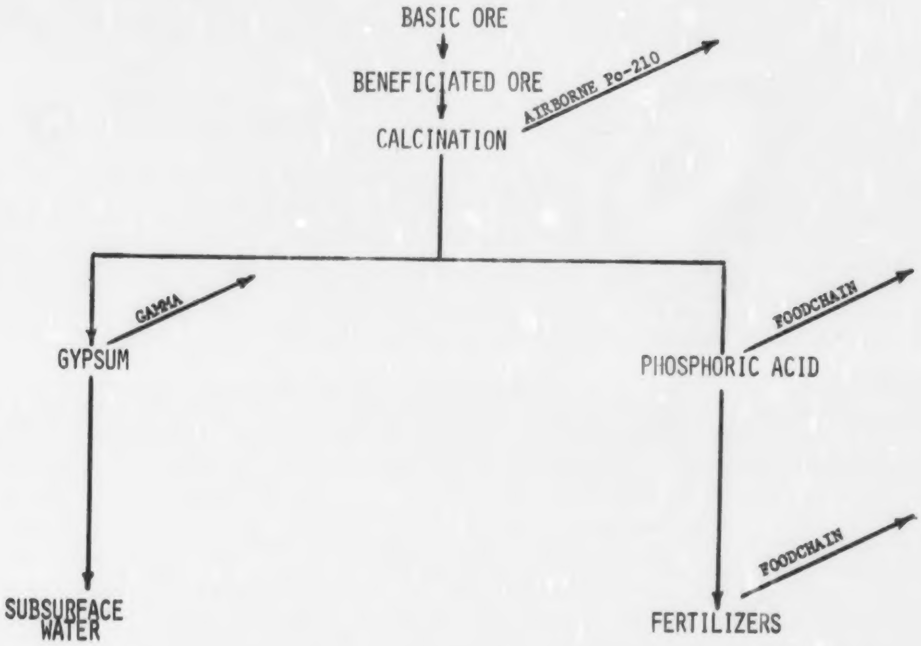

Figure 1. Operation of a wet process plant and the radiation pathways to the environment.

Figure 2 depicts the operations of a thermal process plant and the radioactive pathways to the environment. Basic ore is obtained from Idaho deposits and calcined at 2400° F. Again, polonium-210 is driven off. The calcined ore is mixed with a suitable flux and smelted in large electric furnaces. The smelting of the ore results in Polonium-210 and other radioactive material releases. Elemental phosphorus is condensed out of the furnace stack and is the commercial product of thermal process plants. The main industrial byproducts are slag, a fluid bed material, and the dense metallic bottom layer of the furnace melt called FEP. About 85 percent of the ore that goes to the furnace

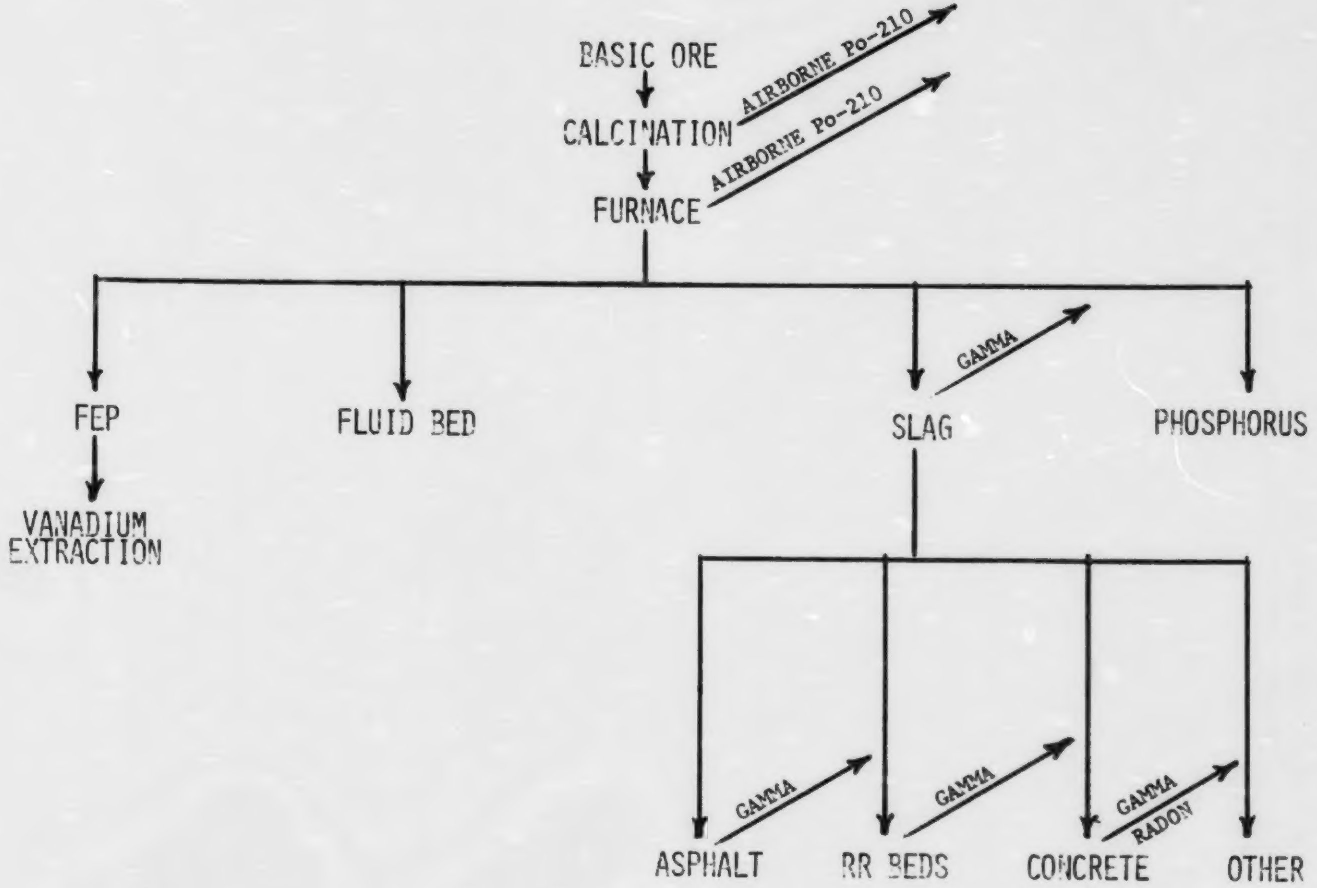
BASIC ORE
CALCINATION
AIRBORNE Po-210
FURNACE
AIRBORNE Po-210
FEP
VANADIUM EXTRACTION
FLUID BED
SLAG
GAMMA
PHOSPHORUS
ASPHALT
GAMMA
RR BEDS
GAMMA
CONCRETE
GAMMA
RADON
OTHER

Figure 2. Operation of a thermal process plant and the radiation pathways to the environment.

ends up as slag, which is primarily calcium silicate. About 2.4 x 10^6 tons of slag are produced in Idaho each year. About one-tenth of this slag produced is sold to slag crushing operations that market the material for railroad ballast, asphalt, concrete, and other uses. The slag contains significant concentrations of radium that results in gamma radiation exposures associated with its use and potential radon daughter exposures associated with its use in concrete under dwellings.

Table 1 shows some of the radioactivity content of products and byproducts from a typical thermal process plant. The data indicate that: (1) some polonium-210 is lost during the calcination process; (2) radium is concentrated in the slag; (3) some thorium-230 is lost from the furnace; and (4) most of the polonium-210 is driven out of the furnace and a great deal of it is condensed and collected with the fluid bed material.

Table 1. Radioactivity content of thermal process samples (pCi/g)

Source[a]	U-238	Th-230	Ra-226	Po-210
Shale	22.0 ± 0.4	21.0 ± 0.4	26.0 ± 0.9	25.0 ± 1.8
Nodule	23.0 ± 0.5	24.0 ± 0.5	26.0 ± 0.9	22.0 ± 1.3
Slag	30.0 ± 0.5	20.0 ± 0.4	35.0 ± 1.0	7.5 ± 0.2
FEP	30.0 ± 0.7	0.2 ± 0.1	0.3 ± 0.1	3.2 ± 1.1
Fluid bed	1.3 ± 0.1	3.0 ± 0.2	11.0 ± 0.6	1300.0 ±80.0

[a] Shale is the basic ore as it comes to the plant. Nodule is the calcined ore. Slag is the main waste product from electric furnaces. FEP is the dense metallic bottom layer of the furnace melt. Fluid bed material is essentially dust collected from the clean up of volatized phosphorus. (Errors are 2 sigma.)

Table 2 shows the results of radium analyses on phosphate products and byproducts. The data indicate that slag contains significant concentrations of radium. Gypsum, some fertilizer, and various ores used in the wet and thermal process plants also contain radium.

The uranium as unprocessed and unrefined ore is source material, and as such is exempt from regulations of the U.S. Nuclear Regulatory Commission and Agreement States. However, the radium and other daughters contained in slag, gypsum, and other materials is not exempt from regulatory control. For example, a licensable concentration of radium is 0.1 pCi/g, according to the Idaho Radiation Control Regulations. This means that the radium content of phosphate products and byproducts is as much as 410 times above licensable concentrations of radioactivity. At the present time there are no controls over the use or distribution of radioactive phosphate products or byproducts, although it is clear that such materials are subject to regulation and control.

Table 2. Radium content of products and byproducts from thermal and wet process plants

Sample[a]	Radium-226 (pCi/g)
Slag #1	39 ± 2
Slag #2	41 ± 2
Gypsum	12 ± 1
Fertilizer	1
Fertilizer	10 ± 1
Ore #1	36 ± 2
Ore #2	26 ± 2
Ore #3	21 ± 1

[a] Slag #1 and #2 are composite samples from two different thermal process plants. Ore #1 and ore #2 are composite samples from these same two plants. Ore #3 is a composite from a wet process plant ore pile. (Errors are one sigma due to counting statistics.)

Figure 3 compares gross alpha air concentrations at three locations in Idaho. The bottom curve is at a location removed from all industrial activity and can be considered background. The second curve up is about 15 miles downwind from two adjacent phosphate plants; a wet process plant and a thermal process plant. The top curve is about 1/2 mile downwind from these same two plants. There is an indication that most of the elevated activity is Polonium-210 and that it is coming from the phosphate works *(7)*.

The gross alpha activity indicates that inplant levels of airborne radioactivity concentrations could be significant and could exceed concentration limits specified for unrestricted areas in regulations of the U.S. Nuclear Regulatory Commission and Agreement States. Preliminary results from inplant studies conducted by the Radiation Control Section and the EPA indicate that this is true. (Inplant air data was collected with the permission of the phosphate industries under the agreement that all data is proprietary.) However, the results from inplant air studies are not conclusive due to the limited extent of the sampling. What is needed is periodic and continuous assessment of airborne radioactivity concentrations. This would best be accomplished by the plants themselves, under the direction and control of a radiation regulatory agency.

Table 3 gives the results of gross alpha and beta water analysis from three wells near two adjacent phosphate plants and from two industrial waste ponds at the plants. The beta activity appearing in the old airport well has been identified as potassium-40. If this potassium, which is highly soluble, is entering the groundwater from phosphate ponds or discharges, then an obvious concern is the potential for radioactivity contamination as well. As table 3 indicates, some industrial ponds have significant concentrations of radioactivity.

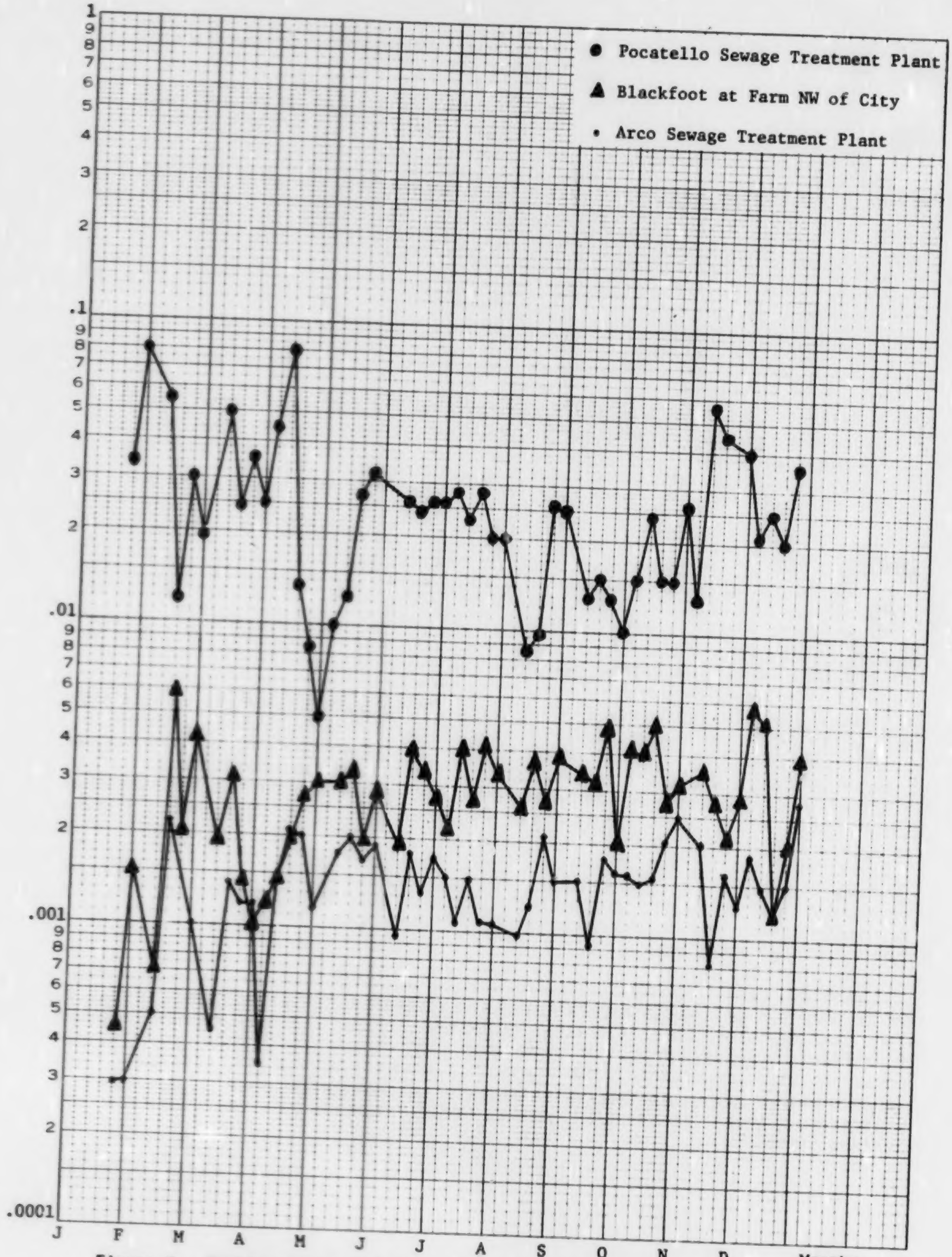

Figure 3. Weekly gross alpha air concentrations-1974 (pCi/m^3). Data taken from the Energy Research and Development Agency off-site monitoring data for the Idaho National Engineering Laboratory.

Table 3. Gross alpha and beta concentrations in water (pCi/l)

Sample	Alpha	Beta
Pocatello Airport[a]	0.3	2.4
Old Airport Well	0.3	198.7
Lindley Well	0.3	6.1
Pond #3	75.0	471.0
Pond #8	254.0	4411.0

[a] The airport well is over 2 miles from two adjacent phosphate plants (wet and thermal). The Lindley well is about a mile from the plants. Both these wells are over 200 feet deep. The old airport well is less than a mile from the plants and is 115 feet deep. The ponds are industrial waste ponds at thermal process plant.

It would be extremely difficult to establish where the potassium (about 250 mg/l) in the old airport well is coming from. In any case, it is obvious that there is a need for continuous monitoring of subsurface waters, ponds, and liquid effluents in order to assess and to keep aware of the potential radiological problems. This would again be best accomplished by the plants themselves under the control and direction of a radiation regulatory agency.

Table 4 depicts the distribution of radium in the environment due to the commercial use of slag in the Pocatello, Idaho area in 1974. This slag and radium is from a single thermal process plant. As the figure indicates, slag is used in city streets, in highways, as fill, in railroad beds, in concrete, and so forth. In this one year, a total of 15,462 millicuries of radium was distributed into the environment in and around Pocatello. So far, only five houses in the Pocatello area are known to have slag in concrete under or within them.

Table 4. Distribution of radium in environs from the commercial use of slag--Pocatello Area, 1974. (Assumes slag contains 35 pCi/g radium)

Use	Location	mCi
Roads	Streets of Pocatello	562.9
Roads	Streets of American Falls	261.0
Roads	Bannock County	5514.2
General construction	Bannock County	886.9
Railroad bedding	Unknown	4741.0
Farmers	Bannock County	1885.7
Concrete	Pocatello	91.6
Miscellaneous	Unknown	1519.0
Total		15462

Table 5 depicts the radium distribution in the Soda Springs, Idaho area due to slag use. A substantial quantity of radium has gone into concrete and a great deal of this is under houses. In the 10 years that slag has been used in the Soda Springs area, it is estimated that 150 dwellings and structures were constructed with slag in concrete.

Table 5. Distribution of radium in environs from the commercial use of slag--Soda Springs area, 1972-74. (Assumes slag contains 35 pCi/g radium)

Use	Location	mCi 1972-74	mCi/Yr.
Roads	Streets of Soda Springs	187.1	46.8
Roads	Streets of Montpelier	148.8	37.2
Roads	Caribou County	8524.9	2131.2
Concrete	Caribou County	1060.7	265.2
General construction	Caribou County	2931.8	732.9
Railroad bedding	Unknown	11430.7	2857.7
Totals		24284	6071

Table 6 gives some gamma levels in the city of Pocatello from the use of slag in asphalt for streets, parking lots, and driveways. The average gross gamma exposure rate 3 feet above asphalt containing slag is about 15 μR/hr and can be as high as 40 μR/hr.

Table 6. Gamma Survey--Pocatello area (corrected gross readings taken 3 feet above surface)

Location	μR/hr
Average background in city	6
Indian Hills School (new asphalt)	9
Cedar Hills Drive	12
Railroad grade throughout city	9
Second Avenue along Ross Park	12
South end of Arthur Avenue	12
Benton Avenue from Arthur to Fifth	23
Yellowstone Avenue	18 to 35
Pocatello Shopping Mall parking lot	37
Holiday Inn parking lot	29
Holiday Inn sidewalk	10
Wilcox School Area	32
Chubbuck School Playground	26
Approximate Average	15

The use of slag-containing radium for road construction and other outdoor uses does not appear to be an immediate radiological problem. The external gamma exposure from continuous occupancy on an average road containing slag would be approximately:

$$15\ \mu R/hr \times 24\ hr/day \times 365\ days/yr = 131\ mR/yr$$

This is below the FRC guideline of 170 mrem/yr for a population group. Even using the maximum exposure rate of 40 μR/hr, the annual exposure for continuous occupancy would be 350 mR/yr. This is below the maximum permissible exposure of 500 mR/yr for any individual in an unrestricted area. (This is the limit specified in regulations of the Nuclear Regulatory Commission and the Agreement States.)

The situation is entirely different with the use of slag in concrete under dwellings. The Radiation Control Section is measuring radon levels in ten structures in the Soda Springs and Pocatello areas. The preliminary results from these studies indicate that gamma radiation levels in dwellings constructed with 43 percent by weight slag in concrete slabs can be as high as 37 μR/hr. Radon daughter levels measured over a period of 6 months have been measured above 0.01 working level. (A working level of 0.01 is the guideline for radon daughter concentrations in dwellings recommended by the Surgeon General in 1970.)

It is expected that no remedial action will be necessary for dwellings having slag under them, but a great deal more data is needed to affirm this. It does appear however, that there is at least a need to control the use of slag in order to restrict its use under or within houses.

Only some of the radiological aspects of Idaho's phosphate and related industries have been discussed in this report. There is an obvious lack of data. I believe that the few data and considerations presented above do indicate a definite need for continuous radiological assessment, periodic monitoring, and restrictions on the use of slag from thermal process plants. These things can best be accomplished through a radiation control program.

One obvious method of achieving the needed control program would be through either general or specific radioactive materials licensing.

Specific licenses could be issued for the naturally occurring radioactive materials in the uranium decay series. The mining, beneficiating, processing, and slag-crushing operations could be licenses to possess, use, and store this radioactive material. Specific licensing could provide for:

(1) Restricted use of industrial byproducts such as slag.

(2) Long-term control of slag and gypsum piles.

(3) Periodic radiation monitoring in order to continuously define and assess radiological problems.

(4) Imposition of radiation regulations and standards.

Safe uses of slag and other radioactive industrial byproducts could be provided for by a general license could: (a) restrict the use of slag to road construction, other outdoor uses, and other uses authorized in writing by the regulatory agency; and (b) prohibit the use of slag for any purpose that would result in or would likely result in slag being under, incorporated into, or within dwellings.

Regardless of the method of achieving controls, I believe controls are needed on the radiological aspects of Idaho's phosphate and related industries in order to eliminate unnecessary radiation and to prevent future problems such as have already occurred with the use of radioactive tailings and other materials.

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REGIONAL APPROACH TO SITING OF NUCLEAR FACILITIES

Dr. Edward Held
U.S. Nuclear Regulatory Commission

To indicate some of the way we are doing things, it is difficult for us to see, or even imagine that things could be otherwise. I believe that is fair to say that it can be otherwise; not only can it be otherwise, but it must be, if we are going to make any progress toward the goal of more efficient, more effective regulation. One way to do this is to view the whole subject from afar, or regional perspective, instead of our current rather narrow approach of facility siting.

How each of us views "regional" is going to depend largely on where he sits. Regional approaches have a potential for increasing our efficiency at all levels of government. They can provide an opportunity for all interested parties to have an input at a time when it really makes a difference. Regional approach is deciding the design, to assure that those with a firsthand knowledge or data get it sent in to the decision-making process early in the entire process of licensing. If conducted efficiently, the approaches can reduce cost, can reduce environmental degradation, and can improve the effectiveness of the decision making.

Let me discuss seed planting and activities in regional siting studies, the nature of our interests in the regional approaches, the expected benefits as we see them, NRC activities that are going on, and to summarize the activitities that are in the planning stage.

Why are we interested in regional approaches to facility siting? We do not select sites. We are not a promotional agency. So, what are our interests? Our interests are to facilitate the licensing process. The issues, as we see them, fall into two broad categories; the procedural issues, including State and local permits, and the technical environmental impact issues, including the social and economical impacts. Common understanding of the procedures required by the States and by the Federal agencies is obviously a must. The streamlining and integration of those procedures as far as possible under existing laws should be of highest priority. Given a good procedural base from which to work, the technical issues, I think, would be resolved any time we are ready. I believe that rational resolution of the environmental impact issues depends significantly on imput at the local, the State, and the regional level. Furthermore, I believe that these issues can be best resolved early in the site selection process before there has been a major commitment of resources by the NRC staff or by the application of construction permits.

The need for streamling of the regulatory process has been indicated by the public, by Congress, by the President, by the utilities, and by the States. The need by the States for clearly defined procedures is certainly documented by the fact that 24 States now have siting authority which includes the siting of nuclear facilities, and 4 States are considering siting legislation. Streamling the process, however, should not ignore legitimate overlapping differences and interests of the local, State, and Federal levels. Many of these issues deal with various impacts on land use. The North Carolina Land Policy Council recently estimated that there are at least 137 Federal programs which have a direct impact on land use. In the same way that some of these programs overlap and conflict, these programs often work at cross purposes with each other, or with State and local objectives. Many of these overlapping issues are on a regional scale. For example, major waterways are frequently the borders between States, and power facilities, because of their need for large volumes of cooling water, are generally sited close to these waterways. The issues that arise are most effectively resolved by early consideration and cooperation, rather than by contention, especially last minute.

Regional approaches will help us fulfill our responsibilities under existing laws with respect to protection of the public health and safety, the common defense and security under the Atomic Energy Act, as we are required to do, and also emissions responsibilities. The benefits that are accrued from our point of view--to do a better job of regulations--include the following:

1. Increase the opportunity for earlier and more effective participation in the licensing process for nuclear facilities by all interested persons.

2. Increase public understanding of the licensing process and hence, public confidence in the process.

3. Enable the Commission to use its resources and perfrom its licensing responsibilities as efficiently as possible.

4. Reduce the burden of the licensing process on the plant and on participants at proceedings by generalizing unnecessary and costly duplication, and reduce the long lead time from the time of identification of the need for the facility to the time the facility is operational.

We believe that regional approaches not only can help us accomplish these objectives, but will, in doing so, improve the quality and the thoroughness of the Commission's regulatory reviews.

Some examples of some more generally applicable benefits that might be expected are money saved in the distribution of costs, savings to the utility and its customers, more effective and more judicious of social, economic, and natural resources (air, water, and land), more effective use of technical and administrative manpower, contribution of information for a regional data base for use in other regulatory type of planning activities, and potential for resolution of generic issues that all parties can agree to and that can reduce case-by-case analysis at all levels of government.

The start of the ladder has been made by a program that NRC's Office of Regulatory Research initiated. Regional programs, conducted by State geologists, working with NRC and with each other, are underway on a geology and seismology as they effect the evaluation of sites for nuclear power plants east of the Rocky Mountains.

What else are we doing in the area of NRC-State cooperation? The Commission has proposed legislation that would prevent advanced planning or early notification or early surveys leading to early site approval and to the standardization of utilization of production facilities. The Act would specifically contain a section for Federal-State cooperation. The Commission would be authorized to conduct the planning and scheduling of reviews and proceedings with those in the States as a consolidated series with those in the States whereever possible--once the State has the legislation. It is very unlikely that it will pass this year. However, even without new legislation, if we can improve the dialogue between the States, between the Federal agencies, and between the States and Federal agencies, I think there is a long way to go. But who knows; perhaps the need for the legislation might go away.

Our activities that go beyond the legislation quality, the technical or assistance areas; one of these has been involved in several studies of siting methodoloy. Let me hasten to say that we are not promoting the development of specific methodology; rather, we seek to identify in the display criteria by which the effectiveness of the site selection methodology might be judged. One such study has been going on between NRC and Maryland, so that we may learn as much as possible from Maryland's experience of evaluating, selecting, and ultimately purchasing sites.

The Maryland program is closely related to an NRC program for early site reviews; that is, you review a site before a specific power facility is proposed for that site. You do have to know something about the characteristics of the proposed facility before you can intelligently select a site. One of our early efforts was the preparation of a staff report on the plant performance characteristics of nuclear power plants. That was issued in 1975. This effort is being built upon and updated, using it for additional plants, earlier studies, and many parameters, and has gone beyond the abilities or the resources of our own staff, and we are doing this with a contract with Argonne National Laboratory.

One of our staff members, building on a report published by the Atomic Industrial Forum, on generalized methodologies for nuclear power plant site selection, prepared this inhouse paper, referencing existing siting methodologies. From this has grown a contract with Sandia Corporation in Albuquerque to provide us with a report that will give us a better understanding of the criteria that are used in developing site selection methodology; or as I said earlier, criteria which will help us to judge the adequacy of the site selection methodology.

The things I have been talking about refer primarily to technical issues, and the technical issues, relatively speaking, are not difficult to revolve in terms of reaching agreements on purely technical and scientific basis. The greatest difficulty appears to be in our getting together; States getting together, our getting together with the States, and the State and local governments getting together in such a way that we can all identify issues earlier, that we can set about resolving them together, that they agree on the kinds of information needed, and on any other details that are needed. A possible model would be something like the Council of State Governments. An ultimate goal would be joint hearings, based on an open approach to the site selection and evalation of the same, but rather than contention after a site is selected when the local developer or utility is making retorical speeches about the local government, the local government complains about the county planners, who in turn speak about reemption of their rights by the State, who complain about the reemption of their rights by the Feds.

What I am talking about, of course, is institutional approaches for the evaluation of the licensing of sites. As a beginning, following from the Maryland study, which was a one-on-one between NRC and the State, we started a study with the Southern Interstate Nuclear Board in 1975. The study looked into the methods for active growing participation by the States, the Federal agencies, and the utilities, and from that study, a regional siting procedure that is potential viable was developed. The study will not be continued in the form of a demonstration program by SINB, supported, in part, by NRC, to select the program involving the utility and two or more States. The program should display the problems that are encountered, and more important, the means by which those problems are resolved in the course of selecting and evaluating sites for nuclear facilities on a regional basis. A similar study is just getting underway with the Western Interstate Nuclear Board. In fact, the contract was just approved at the beginning of this week. The first part of that study will include, as did the SINB study, identification of the issues that are of particular concern of the Western States.

In summary, let me repeat what I said in the beginning, I believe that the best resolution of an environmental impact issue depends significantly on input from the local, State, and regional level. Furthermore, I believe that these issues can be best resolved with maximum objectivity and minimum cost early in the site selection process. Proposed legislation appears to have little chance of enactment soon. By working together, there is a lot that can be done within the framework of existing legislation. We are committed to work with all interested parties, through regional approaches to nuclear power plant siting and nuclear facility siting, both technical and institutional, and to give an opportunity for all interested parties to have input early in the licensing process and to make certain that those with first hand, local knowledge have an opportunity to present the information at their command before the issues are in serious contention. The State and local governments must provide the needed mechanism to make this licensing process work; only they can bridge the gap between industry and NRC. To do it we must have cooperation among us all; industry, Federal agencies, and especially among the States themselves.

TERMINAL STORAGE OF RADIOACTIVE WASTE

Carl Kuhlman
Division of Nuclear Fuel Cycle and Production
Energy Research and Development Administration
(presented by Mr. Wayne Knowles)

Concern over radioactive waste management, especially over the final disposal of high-level waste, has been conspicuous in the arguments against commercial nuclear power. The Energy Research and Development Administration (ERDA) recognizes this critical area and has proposed a major national initiative for solution of EDRA's part of the problem.

Figure 1 shows in gross numbers the magnitude of this initiative. The President's proposed budget for Fiscal Year 1977 totals $90 million for commercial and ERDA-generated waste compared to a Fiscal Year 1976 budget of just under $31 million--an increase by a factor of three. The increased emphasis on the commercial waste is even more dramatic--a factor of five.

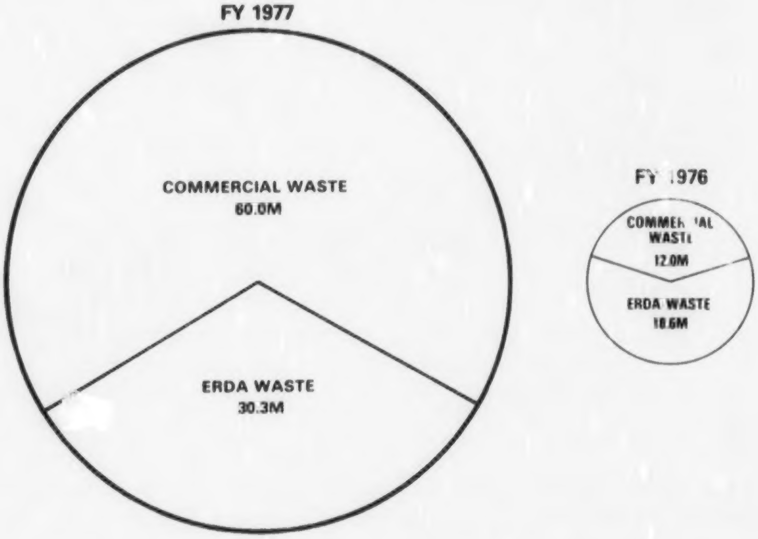


Figure 1. Waste management operating budget.

This presentation will focus on ERDA's Terminal Storage Program for commercially generated high-level and transuranic-contaminated waste. It will not address ERDA's program for ERDA-generated waste, uranium mill tailings or "low-level" burial grounds even though ERDA recognizes there are controversies about the last two items.

What is the magnitude of the high-level waste problem? Most of the commercial high-level waste has yet to be generated. A typical 1000 Megawatt (electrical) reactor will eventually be responsible at the fuel reprocessing plant for about 65 cubic feet of solidified high-level waste per year. A recent projection (Fig. 2) shows the cumulative United States inventory by the year 2000 to be a volume roughly equal to a football field piled 5 feet deep. This is obviously not an overwhelming volume problem. It is, however, certainly a confinement problem. Typical high-level waste will need to be isolated from man's environment for periods of time which are extremely long compared to periods of time considered in other human affairs. Long though this period of isolation is, it is not, however, truly infinite as in the case for nonradioactive wastes containing elements such as lead, mercury or other poisonous substances.

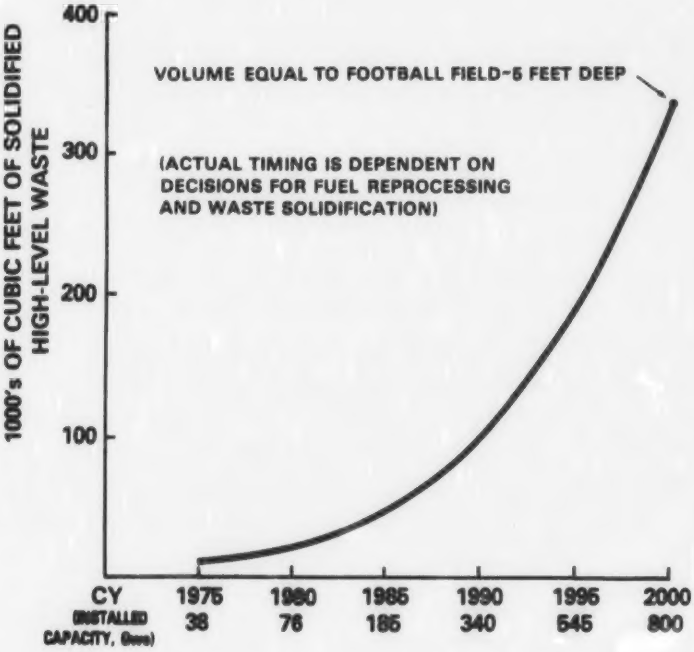


Figure 2. Volume of solidified high-level radioactive waste accumulated.* (*W/O interim storage as liquid.) 3/1/76

Our view of confinement is shown in figure 3. When the waste is placed into a stable solid form to minimize risks of dispersal during storage or transport, and then placed within a high-quality engineered structure, it is isolated from the environment for at least hundreds of years, a period set by assumptions of political and social order. This approach would still place some maintenance burden on future generations. It is only by providing the further isolation of a deep, stable geological formation that we believe it will be possible in the near future to eliminate this maintenance burden.

The new ERDA Waste Management Program as described in the FY 77 budget provides for the assurance that technology exists for processing all of the waste streams from the back end of the fuel cycle into forms in which the waste can be safely handled, transported, and disposed of. The ERDA program also provides for the establishment of a repository for isolation of the high-level waste. It is this terminal storage part of the program I plan to discuss today.

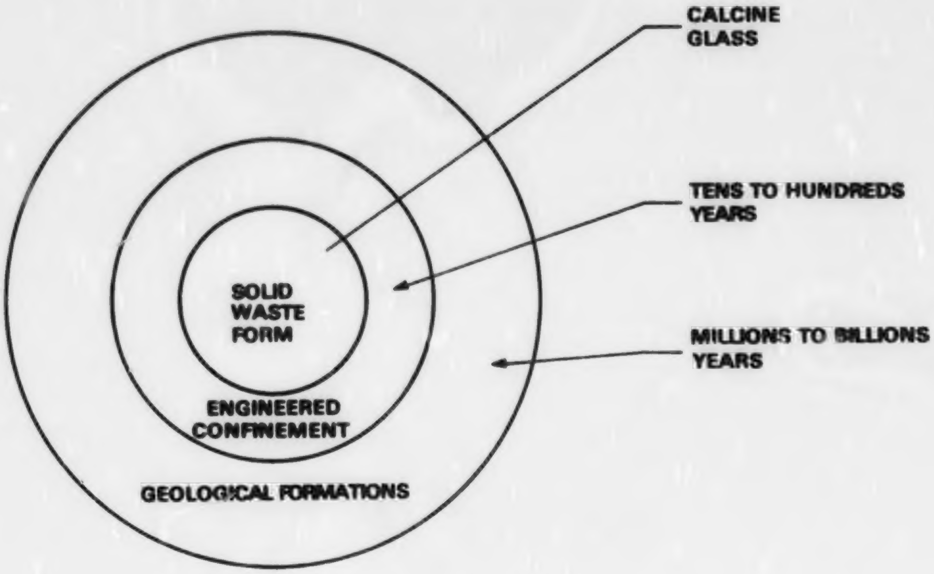
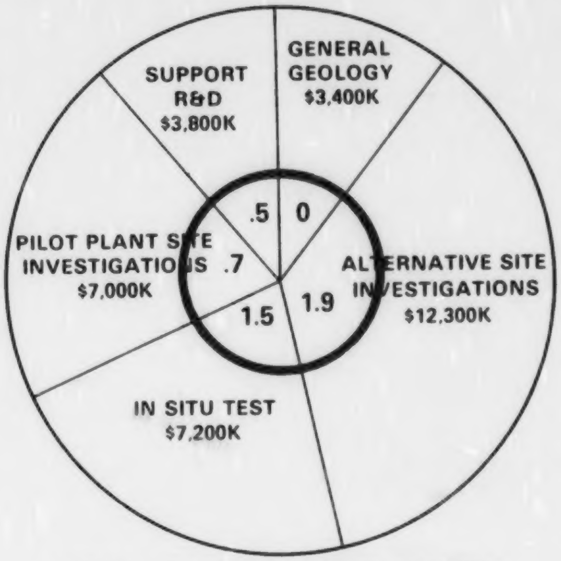


Figure 3. Barriers to the environment.

The terminal storage part of the waste management program differs from that for waste processing in that the Government, not industry, is to be the repository operator.

The basic objective of the terminal storage program as now conceived by ERDA is to provide multiple terminal storage sites in a time frame that does not inhibit the development of the nuclear power industry. I would like to emphasize that the ERDA program contemplates the establishment of several repositories--not a single repository. Furthermore, the development of these several repositories will proceed simultaneously--not sequentially. Figure 4 shows the magnitude of the proposed FY 1977 program with the smaller circle showing the corresponding FY 1976 budget. There are a number of reasons for adopting a program of simultaneously pursuing a search for several sites. A multiple site approach to the Terminal Storage Program (1) assures timely demonstration of terminal storage, (2) reduces risk of political failure, (3) eliminates the stigma of one site receiving the Nation's waste, (4) reduces transportation cost and risk, and (5) permits a retrievability concept. The program is designed so that no single disappointment will have a major impact on the overall program schedule. It reduces the risk of political failure by depolarizing the climate in any given area. No one locality will have the feeling that it is receiving all of the Nation's nuclear waste. Finally, if areas are encountered in which political impediments arise, presumably there will be other areas in the program which will be free from such obstacles. The wide geographical distribution of terminal storage facilities will, of course, reduce the cost of transportation. Finally, the retrievability concept is enhanced if there are at least two repositories.



TOTAL FY 1977 BUDGET $33,700K
TOTAL FY 1976 BUDGET $4.6K

Figure 4. Terminal storage program elements and FY 1977 budget.

Now let's look at the parts of the program with the aid of figure 5. Figure 5 breaks up the program into the same categories that you saw in the budget (Fig. 4). The General Geology part involves a general survey of all major geologic formations within the continental United States to provide appropriate locations for more detailed investigations. While it is shown as terminating in 1980, in actual fact, of course, this kind of work will be continuing throughout the terminal storage program to a more or less degree. On the basis of the general geology survey, many locations will be studied prior to reduction in number for the more concentrated investigation phase of the program. An alternative site would be of the order of four townships in size. The number of sites will be progressively reduced in number as the program progresses into the more intensive investigations. As representative geologic formations are selected, a program of in situ experimentation will be initiated which, in its more simple terms, will provide experimental confirmation of the laboratory and theoretical predictions of the response of the selected geologic formation to radiation and temperature. The site investigations and in situ experimentation will culminate in the construction of terminal storage pilot plants. You will note that the program comtemplates the operation of the first pilot facility in the mid-1980's. The pilot plant site and facilities will be selected on the basis of qualifying as a final terminal storage site and facility. However, the pilot plant facility will be engineered, designed, and operated under conditions that permit retrieval of the stored waste in the event of unforeseen circumstances. After the pilot plant demonstrations are completed and the facility licensed for permanent waste emplacement, the retrievability feature will be abandoned. These pilot plants will require a significant portion, if not all, of the high-level waste generated in the early 1980's as part of their confirmation program.

The terminal storage pilot plant effort would be supplemented by a supporting technology effort--not necessarily at the same site--on such matters as borehole plugging, waste diffusion, waste retrieval, and many other subjects.

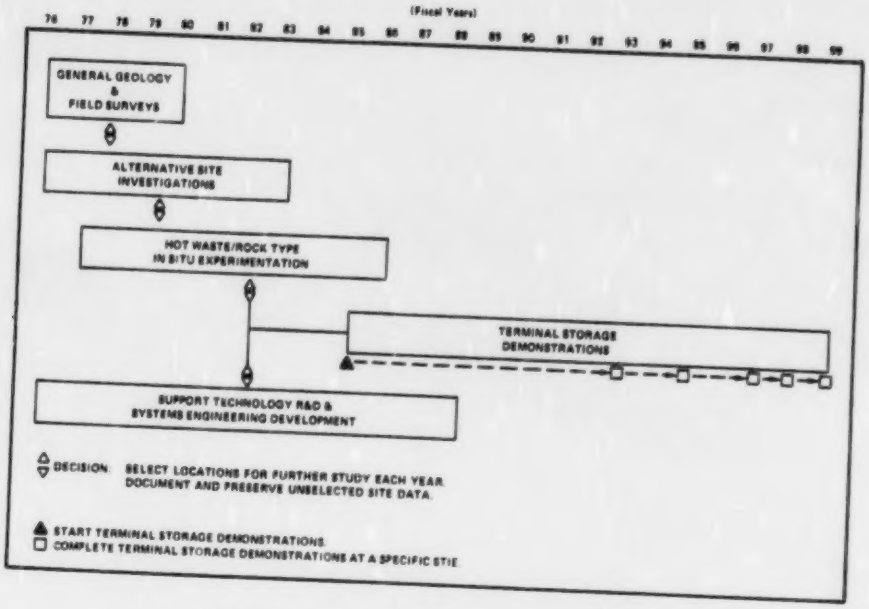


Figure 5. Terminal storage program.

The next several figures illustrate the wide variety of options that are available to us for the selection of a repository area. Figure 6 shows the rock salt deposits throughout the United States. Salt beds were selected for the Lyons, Kansas, project and they still remain the most advanced of the options in the program. We are also considering the crystalline formations shown in figure 7 which now introduces options in the western and southeastern parts of the country that did not have salt. Finally, we have the argillaceous formations (Fig. 8) in the United States. Thus, consideration of all these types of formations provides wide geographical option for waste repository. Furthermore, much smaller examples of these formations than shown on these maps can suffice for a repository.

To place the terminal storage program in context with the needs of industry, figure 9 was constructed to show the earliest possible sequence of events that could lead to a need for the terminal repository. We assume the NRC decision on the Generic Environmental Statement on Mixed Oxide (GESMO) defines the earliest time at which reprocessing could start. Approximately 5 years is assumed for design, construction, and licensing of high-level liquid waste solidification capability. This 5 years just happens to coincide with the maximum time the present regulation permits the reprocessor to keep the waste as a liquid. He must then solidify it and then may store it another 5 years at his reprocessing plant. This then gives a "can ship" date and a "must ship" date. The next line on the chart shows a terminal storage facility available to accept waste on a test or demonstration basis and is expected to come into being somewhere between the most optimistic dates at which a reprocessing plant could ship and must ship. For possible requirement of earlier capability or for reserve storage capability for geological repository test inventories, we have the retrievable surface storage concepts for which technology is being completed and will be kept available.

In summary, the proposed FY 1977 ERDA waste management program comprehensively addresses all of the waste technology problems identified with the post-

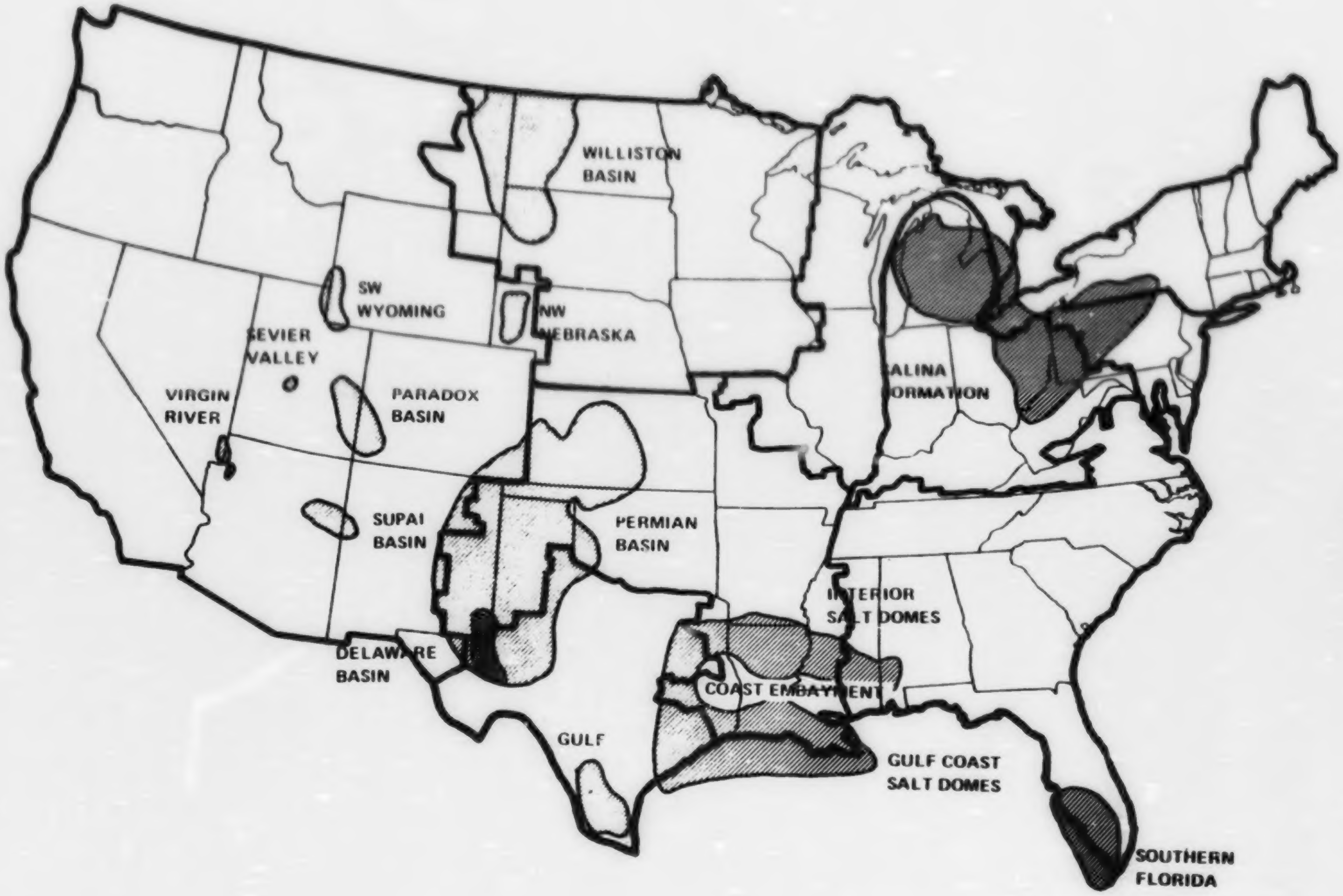

WILLISTON BASIN
SW WYOMING
NW NEBRASKA
SEVIER VALLEY
VIRGIN RIVER
PARADOX BASIN
SUPAI BASIN
PERMIAN BASIN
DELAWARE BASIN
GULF
SALINA FORMATION
INTERIOR SALT DOMES
COAST EMBAYMENT
GULF COAST SALT DOMES
SOUTHERN FLORIDA

Figure 6. Rock salt deposits in the United States (after Pierce and Rich, U.S.G.S. BULL. 1148).

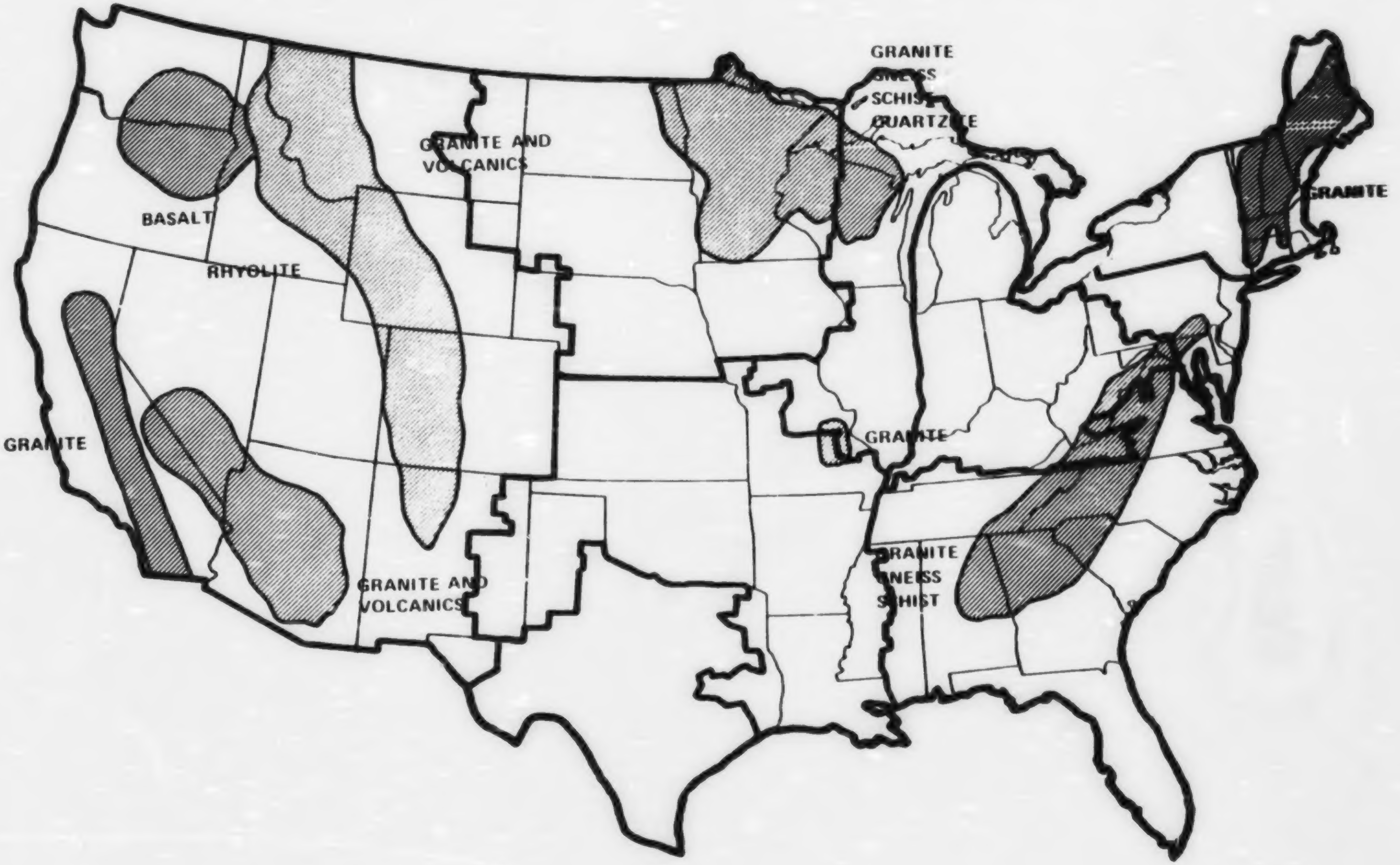

GRANITE
GNEISS
SCHIST
QUARTZITE
GRANITE
GRANITE AND
VOLCANICS
BASALT
RHYOLITE
GRANITE
GRANITE
GRANITE AND
VOLCANICS
GRANITE
GNEISS
SCHIST

Figure 7. Crystalline formations in the United States.

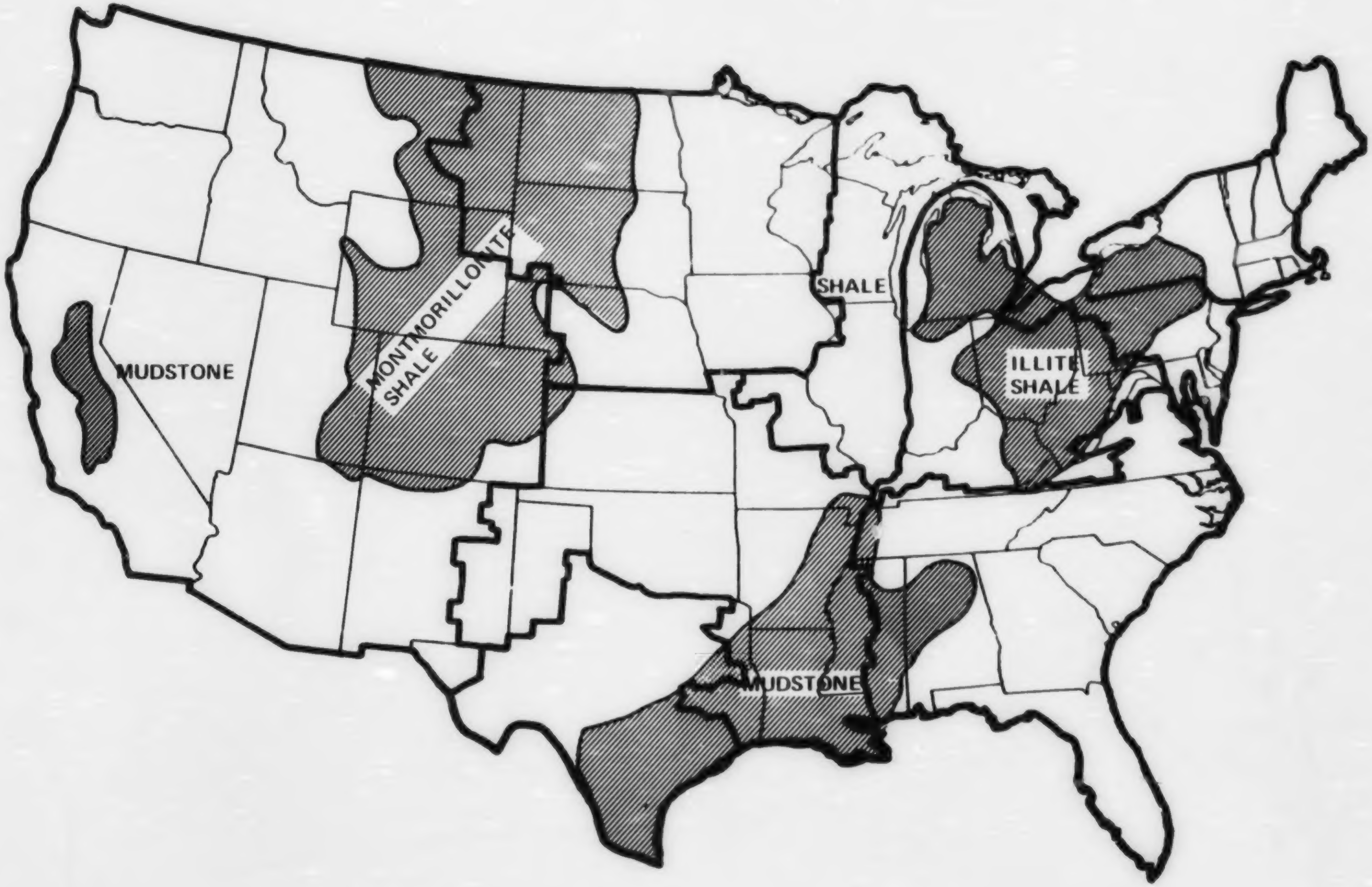

MONTMORILLONITE
SHALE
MUDSTONE
SHALE
ILLITE
SHALE
MUDSTONE

Figure 8. Argillaceous formations in the United States.

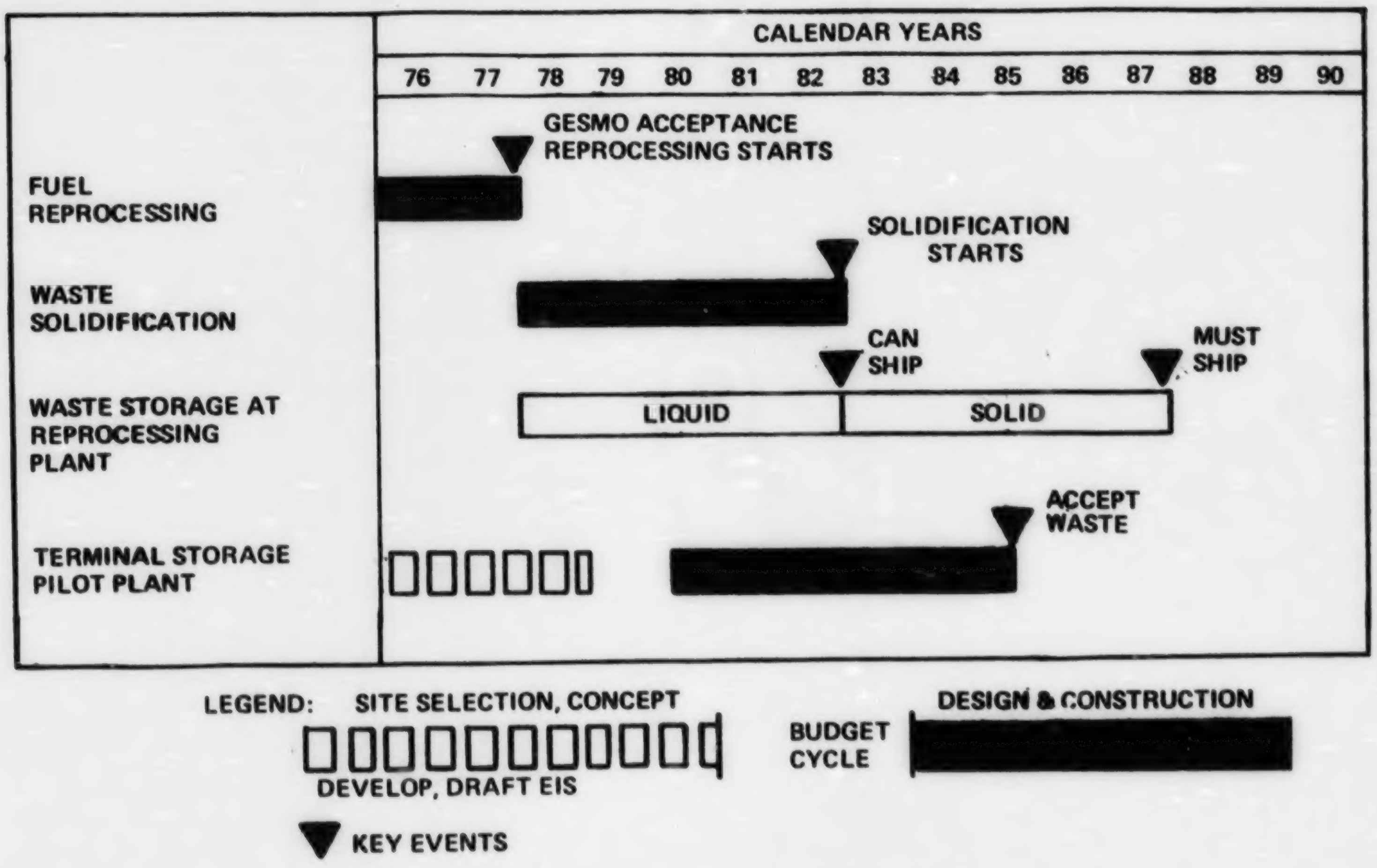


Figure 9. Fuel reprocessing/waste storage.

reactor part of the fuel cycle. Technology will be developed for the use of private industry to convert each of the various waste streams into forms in which they may be safely transported and terminally stored. A number of U.S. areas have been identified as underlain by geological formations with the theoretical properties desired for a terminal repository. The scheduled program, assuming continuation of the momentum proposed by the 1977 Presidential budget, provides an excellent prospect of having several repositories constructed in time to receive the waste when it must be shipped by commercial processing facilities. Finally, improved communications are planned with State, local, and regional officials and members of the general public to maximize the chances of this vital program being accepted on both technical and nontechnical bases.

DISCUSSION

MR. KERR: What about the practical aspects of getting a place for the storage and having it accepted and located?

MR. KNOWLES: We had three locations--one in Idaho, one in Washington, and one in Nevada--as ERDA sites. These are still locations to be evaluated, should we get to that alternative.

MR. KERR: I have attended a previous meeting where these were discussed. What are the practical aspects of getting one approved; do you think it will be approved?

MR. KNOWLES: Presently, we are not contemplating the need for retrieval storage facilities; that is, we do not plan to exercise that option, unless we get some kind of early delivery of waste, or unless there is some hangup in this terminal storage program. I would think that with the proper legwork, we will prepare the proper environmental impact statements to get the sites approved.

MR. ROBERTS: Apparently ERDA's program is based on the assumption that spent fuel will be reprocessed. I think you made a statement that you believe that all spent fuel can be processed. There is an alternative, of course, of not reprocessing. Has that alternative been evaluated sufficiently to arrive at the conclusion that spent fuel should be reprocessed?

MR. KNOWLES: Of course, this is not our option to make that decision one way or another. These facilities and terminal storage sitings would accomodate spent fuel as spent fuel should that decision be made. It has not been evaluated in detail.

MR. ROBERTS: I understand that you are working on environmental impact statements on this subject. I also understand that NRC and ERDA will collaborate on that. Will the option of not reprocessing be considered in the environmental statement--the cost-benefit?

MR. KNOWLES: I would imagine that would be the case. The last environmental impact statement we put out, there seems to be a lot of loose ends of that sort. A new environmental impact statement in preparation is going to NRC and ERDA to answer and I am sure that subject will be covered.

MR. REILLY: You are talking here about ultimate disposal of high-level waste. I think one of us here might be facing now, or expect to face the matter of storage of the so-called low-level stuff, which accumulates to the tune of 30,000 cubic feet a year, and all of this. We sort of envision that perhaps there might be a case of acute constipation in that aspect of the fuel cycle. Can we look forward in the next few years to getting some kind of reasonable criteria for land disposal of this so-called low-level stuff?

MR. KNOWLES: Yes, there will be criteria prepared for that. There are a number of studies being conducted within waste management on near surface land burial. On the other side of the picture, there are proposed regulations that say that the transuranic contaminated wastes from commercial industries will be sent to ERDA. Transuranic contaminated wastes will be included in these terminal storage facilities. So, when I speak of high-level wastes, that is light level, because we include all transuranic contaminated wastes.

COMPREHENSIVE RADIATION ASSESSMENT STUDY (CRAS)

James A. Blackburn
Illinois Department of Public Health

On December 18, 1972, the Illinois Department of Public Health signed a contract with the Office of Radiation Programs of the U.S. Environmental Protection Agency to develop what became known as the Comprehensive Radiation Assessment Study. The purpose of this study was to develop a mechanism whereby the radiation exposure received by the general population could be correlated to show the relative impact of the many diverse sources contributing to this general exposure. In the original proposal, the Department indicated that such a study would take approximately 3 years. Because of budgetary restrictions, the entire study could not be funded. However, a 1-year pilot study was negotiated to design and test the radiation assessment model. This presentation will be based on the findings of that pilot study.

It became obvious during the initial planning of this study that many potential sources of ionizing radiation were relatively simple to identify and categorize. For the purposes of this study, the radiation exposure was separated into four major categories: (a) Environmental, (b) Occupational, (c) Medical, and (d) Consumer Products.

The first activity to be undertaken in obtaining the exposure data was to document precisely the methodology of measuring the exposure levels. It was decided that a single exposure medium would be used as much as possible with a single calibration source used for standardization. In this way, although the calibration method and the precision obtained may be debatable, the relative exposure values as they relate to each other should remain a fixed constant. We elected to utilize TLD 100 in the ribbon configuration as supplies by Harshaw Chemical. The holder for the TLD was designed by this Department for use during its environmental surveillance activities. The holder was made of ABS (acrylonitrile butadiene-styrene) plastic with a shielding thickness of 0.025 inches. The TLD and the holders were submitted to the Division of Electronic Products of the Bureau of Radiological Health, FDA for exposure and calibration. The analysis of the resulting data indicated that although the holders showed slight energy dependence below 26 KeV, the TLD still recorded approximately 95 percent of the total exposure at 21 KeV.

The evaluation of medical examinations was accomplished using the NEXT (Nationwide Evaluation of X-Ray Trends) test stand and the associated data processing. The initial sampling program was not intended to be a vehicle through which statistically valid data would be gathered, but rather a testing mechanism to determine if such a program could be established. This sampling was done in an 18-county area located in the west central portion of Illinois. This section had a population of approximately 650,000 people and a wide range of radiation facilities.

To sample the environmental radiation, a total of 100 environmental foci were established. These foci were located to reflect the population density throughout the region. One focus was established for each 5,000 population except in municipalities. At least one focus was established within each county regardless of the population of that county. The following samples were taken at each environmental focus:

1. Environmental - A dosimeter was placed on dead wood at a height of approximately 6 feet to measure the natural background of radiation. These locations were exterior to any buildings and unaffected by any known radiation source.

2. Housing - The monitoring of housing consisted of sampling both a frame house and a masonry house at each environmental focus. The masonry house was required to be either solid masonry or to have brick veneer on all four sides to a height sufficient to enclose the first floor area.

3. Electronic Products - The presence of electronic products in the form of television receivers was also to be included. Color television sets were preferentially sampled over black and white sets with the largest and/or oldest color set receiving the highest priority.

4. Personnel - For this purpose one member of each household contacted to represent the housing within the region was requested to carry a thermoluminescent dosimeter on his person throughout the duration of the study.

The radiation facilities within the region were categorized according to the type of facility, with a random selection made for each of the major medical facility classifications. These classifications were: (1) dental offices; (2) medical offices; and (3) hospitals and clinics. Due to the diversification of industrial applications, no random selections of those facilities was made. Instead, the entire group was included within the study. As a result of this sampling procedure, 39 dental facilities, 36 medical facilities, 24 hospitals and clinics, and 35 industrial radiation facilities were analyzed.

At each of the radiation facilities, whether medical or industrial, one or more environmental dosimeters were located in the immediate environs to reflect any increase in radiation levels as a result of the activities within the radiation facility. In medical institutions, a TLD monitor was also placed in the waiting area especially for those facilities with outpatients. The waiting area of those facilities reflected the closest point that a nonpatient would normally occupy.

In addition, the TLD holders were issued to a representative sample of the or around the radiation sources at that facility. By comparing the exposure received by the employee of the radiation facilities with that of the people at the environmental foci, the magnitude of the occupational component could be determined.

It has long been recognized that the exposure to ionizing radiation as a result of medical practice is the largest component of man-induced radiation exposure. To estimate the magnitude of this segment, documentation as to both the exposure perimeters and the amount of usage was required. Each radiation facility was requested to document the exact usage of its radiation facility for a 1-week period. This usage was obtained through patient records or detailed logs maintained at the controls of each radiation source.

Results

As previously mentioned, the data which resulted from this study must be considered preliminary at best. Additional readings could very well change the results that will be presented. The data that are presented, however, do provide much food for thought for all of us concerned with the exposure to the population from ionizing radiation.

Environmental radiation levels ranged from a minimum of 15.4 mR per quarter to a maximum of 30mR per quarter with a mean value of 20.2 mR. The variations are very graphically portrayed by plotting the actual data values in their respective geographic locations. As can be seen, lower radiation levels apparently exist in a band along the western-most portion of the region then extending diagonally through the region in a northeasterly direction. Conversely, four areas of increased radiation levels also exist within the region. These areas are relatively well separated by levels intermediate in magnitude. Plotting these data on a single map allows the drawing of radiation contours, if desired.

Other data gathered at the environmental foci indicated that the radiation levels within masonry dwellings as compared to frame dwellings showed no significant difference. Likewise, the analysis of radiation emissions from television receivers revealed no general elevation of exposure except from two sets that were leaking significantly. One set in particular yielded a projected annual exposure of 987 milliroentgens. On a followup attempt to monitor the emissions from the set it was learned that the set had apparently malfunctioned since the original data was recorded and had been junked. A second set was also of interest, giving an initial reading of 71.9 mR during the first 6-week exposure period. The second period, however, yielded a value of only 11.9 mR. A followup on this set indicated that the set had been malfunctioning also and had been repaired during the second exposure period.

The occupational exposure truly followed pre-established opinions. In most instances, the maximum values were widely separated from the next highest value. These high values in particular skewed the mean in an upward manner. The mean exposure for the people monitored at the enumerated foci was 76 mR/year.

The analysis of the medical impact involved the correlation and interrelation of several independent variables. These variables included:

1. The frequency with which the particular procedure was performed;

2. The number of exposures comprising the procedure;

3. The intensity of the radiation beam required to perform the procedure; and

4. The amount of the body subjected to the direct radiation beam.

An analysis of the examinations indicates that three procedures (bitewing examinations, chest examinations, and periapical examinations) comprise over 50 percent of the medical diagnostic procedures performed within the region. Extrapolating the frequency with which the procedures were performed, a total of 760.000 radiological examinations would be performed per year in the sampling region. This is a sizable number of procedures for a population of 650,000 people.

Since the frequency that an exam is performed has no bearing upon the amount of radiation received by the patient, other factors must also be considered. Ranking the examinations by the radiation intensity coupled with the size of the radiation beam striking the patient gave a completely different ranking. Bitewing examinations, for instance, ranked only 32nd when rated by this method.

On evaluating the impact from a specific procedure, the evaluation must also consider what comprises this specific exam. The radiographic examination of ribs, for example, consists of a single anterio-posterior projection if performed in the average medical office within the region. If performed at the average hospital, however, the same exam consisted of two AP and two oblique projections. This results in a 10-fold increase in the radiation exposure received by the patient if the exam is performed at a hospital rather than at the doctor's office. This analysis of the "ribs" exam is not a unique one. The same differences are also apparent in "Thoracic Spines," "Lumbar Spine," and "Chests," although not to such an extent.

Taking all these variables into account, the projected impact of the various radiological procedures was determined. Once again, three procedures (upper gastro-intestinal, lumbar spine, and lower gastro-intestinal) comprised over 50 percent of the projected impact from diagnostic radiological procedures.

Our final activity under this contract was to attempt to compare the population exposure from the various sources of radiation. To compare the whole body radiation encountered in the natural environment with partial body radiation used during medical procedures, is a difficult if not an impossible task. This Department used the surface exposure integral (SEI), which is defined as the intensity of the radiation as expressed in Roentgens multiplied by the exposure area of the body being irradiated as expressed in centimeters-squared. This concept was carried one step further and a new index was defined. This index was established using the Greek letter psi as the basic unit of measurement. Psi is defined as that exposure value equal to a surface exposure integral of 1 mR to the whole body or 18 R-cm^2.

We recognize that this type of mathematical gymnastics is based upon certain assumptions which are dubious as to their validity. It does, however, provide a mechanism whereby various types of radiation can be correlated and compared. Comparing the psi values for environmental, occupational, and medical exposures indicates on the surface that medical exposure outweighed even the environmental component significantly. Analyzing the medical exposure by source type, however, quickly identifies the majority of such radiation from therapeutic treatments. Further analysis of the radiographic exposure by facility type indicates that approximately 80 percent of all medical exposure is given in hospitals.

It must also be noted that the exposure identified as fluoroscopic includes all aspects of a fluoroscopy procedure even though much of the procedure is radiographic in nature (i.e., spot films and overheads). Analyzing this exposure by its various components indicates that the exposure is fairly evenly distributed among the actual fluoroscopy, the spot films, and the overhead projections.

An exposure index was also calculated for each county within the region. The values ranged from 209.7 to 239.4 with a regional average of 221.9. In conclusion, I would like to spend just a minute discussing an incident that recently occurred within Illinois that graphically displays the tunnel vision we so frequently encounter and experience in the radiation area. An employee of one of our manufacturing firms inadvertently swallowed two small metallic foils, approximately 2 millimeters in diameter, each containing 2.5 microcuries of americium-241. When the incident became known to the president of the firm several days after its occurrence, the consulting health physicist was notified and the patient was rushed to an area hospital. There the employee was subjected to a fluoroscopic examination in an attempt to locate the source. After the fluoroscopy was completed, everyone was reassured that the sources had passed and were no longer within the patient. A whole body count subsequently performed at the Argonne National Laboratory, however, graphically revealed that this was not the case, the sources were indeed still located within the employee. As a result, stool specimens were collected until such time as the sources did in fact pass from the body.

DISCUSSION

DR. SOLON: Would the ranking be the same if you used another index (conceivably the genetic or gonadal dose), rather than the integrated area exposure?

MR. BLACKBURN: No, because if you use the genetic, of course, that would depend upon which part of the body it was affecting; such as, bitewing then, regardless of the intensity or the area would add nothing; the same for skull series.

DR. SOLON: Right. I was wondering why the area exposure index apparently took priority.

MR. BLACKBURN: We used the area exposure simply because the basis for this study was to try to correlate all types of exposure together, and since the environmental, the occupational, and everything else, was somatic or total body, we wanted to basically be able to correlate the medical with that type of situation.

U.S. NUCLEAR REGULATORY COMMISSION'S NUCLEAR INDUSTRY STANDARDS ACTIVITIES

Craig Roberts
Division of Siting, Health, and Safeguards Standards
U.S. Nuclear Regulatory Commission

Today, I wish to accomplish two things: give you a summary of the national standards effort and present an overview of the inhouse NRC standards effort. In the time I have, I just want to touch on the highlights and to give you examples of activities underway. To do this, I have organized my remarks accordingly to four categories of products or standards; water reactors, fuel cycle facilities, siting and health standards, and safeguard standards.

First, I want to tell you that the primary objectives of the NRC standards development program are to fulfill the agency mandate to stabilize the process of regulating nuclear materials and facilities, and to effectively and efficiently utilize resources to carry out that process. Several years ago, the old AEC challenged the industry to codify lessons of experience and good engineering practice that had been accumulated by the industry. The industry accepted that challenge and formed a number of work groups involving over 8,000 specialists. Since that time they have developed over 350 nuclear standards, many of which should be useful to the State agencies represented here. Two hundred of those national standards, after careful review by the NRC staff, have either been endorsed or referenced, after public review and comment, in NRC regulations and guides.

The principal ANSI committees of interest to this group would be N13, Radiation Protection, which is under the Secretariat of the Health Physics Society; N14, Transportation of Fissile and Radioactive Materials, under the American Insurance Association; N18, Nuclear Design Criteria; and N19, Nonradiological and Environmental Effects. During the period of accelerated national standards effort, the NRC staff has issued over 100 regulatory guides in all categories, but principally in water reactors--water reactor safety and safety analysis.

Some notable accomplishments in that area include a guide to standardize format and content of power reactor license applications, which you are probably familiar with it. It has received several iterations of public comment. In the interest of establishing a stabilized and predictable basis of regulatory review and acceptance, the staff of NRC's Office of Nuclear Reactor Regulation has developed and issued a standard review plan for providing definitive guidance to the staff and to the public on conduct of reviews and the criteria of acceptability. Similarly, the Office of Inspection and Enforcement has developed definitive staff guidelines for the conduct of inspections. This progress in the water reactor standards area has resulted in a shifting of the emphasis from one of developing new to improving and updating existing standards.

In the fuel cycle standards area, we are not as well advanced as we are in light water reactors. The diversity of operations and practices, the small number of plants of any one type, and the lack of broad experience limit the capability for developing definitive numeric standards and the lower priority given to their development. For the near term, the greatest potential value of fuel cycle standards seems to be in the clarification of regulatory requirements and as a vehicle for codifying and defining sound methodology in the design, construction, operation, and safeguarding of those facilities. Two amendments to our rules, one for general design criteria and the other emergency plans for mixed oxide fuel plants, have been issued for public comment.

At this point, I think it is appropriate to mention something about transportation within the fuel cycle category. With continuing focus by the public and the Congress on transportation of radioactive materials, we have undertaken a reevaluation of pertinent NRC regulations and issued a draft generic environmental impact statement, including a shipment survey, on the air transportation of radioactive materials, with particular emphasis on standards related to packaging.

In the siting and health standards area, which is my specialty, fewer national standards have been produced than is the case with engineering standards, because there has not been the same background of information and standards writing effort to draw on, and many of the topics are unique. However, working groups have been established for some time, staffed with highly qualified personnel, and products are beginning to come out of the pipeline. I am a member of ANS-2, which is Site Safety Evaluation Standards, so I am particularly familiar with the work of that committee. They have issued one standard on earthquake instrumentations for nuclear power facilities, and another on the design basis for flooding determination is in the ballot stage. A standard, not of the ANS-2 but of particular interest to this Conference, is N237, which establishes typical long-term concentrations of principal radionuclides in reactor fluid streams and can be used to estimate expected releases of radioactive materials by effluent streams. We used that standard as the computational basis for two new regulatory reports, which were issued in conjunction with Reg Guide 1.112, "Calculation of Releases of Radioactive Materials and Gaseous and Liquid Effluents from Light Water Cooled Reactors," which is one of five implementing guides for Appendix I. Four of those five guides (dose calculations, atmospheric diffusion, source terms, and aqueous pathways) have been issued. Two other important guides that are involved in the implementation of Appendix I are Regulatory Guide 4.8, "Preparation of Environmental Technical Specifications," and 4.2, "Preparation of Environmental Reports." Both were issued for public comment in the recent past, but now have been revised to implement Appendix I. Provision 2 of 4.2 will be issued in the near future. Regulatory Guide 4.8 will be a little slower coming out; the public comments received on it were considerable, and the major comment was related to the duplication of regulation between NRC's Environmental Technical Specification license conditions and the EPA and State's permits. There is a very penetrating discussion underway within the NRC staff on that issue.

You are probably all familiar with our site evaluation regulations, Part 50 and Part 100, and know that there is a standard review plan in place for staff review of site criteria. I mentioned it earlier in connnection with the light water reactor standards. Regulatory Guide 4.7, "General Site Suitability Criteria," was issued more than a year ago. There is also a series of guides to assess design events, particularly floods, hydrologic design criteria, and protection of all the heat sinks.

Several important radiation protection activities are underway. You will recall that the former AEC announced proposed rulemaking to implement NCRP recommendation on limiting the dose to the fetus of occupationally exposed pregnant women. Many comments were received, and a proposed regulation is in for final Commission consideration. Also, we have a petition inhouse to reduce the occupational exposure limit. Further, we are deeply interested in controlling transit worker exposure and we have identified a number of alternative methods for doing that; evaluating the value impact of each. In that connection, we met with the Atomic Industrial Forum's Environmental Committee last week, and asked for their analysis and input on value impact of the alternatives we have identified. The Commission just recently acted on a petition to reduce the exposure limit to insoluble inhaled plutonium particles--the so-called "hot particle" issue.

Turning to the safeguard standards that area is in a developmental stage. There are three components to the subject; materials control, material accounting, and physical protection. A technical basis is now being developed for regulations and guides in that area, on an interim basis.

New regulations covering nuclear reactor physical protection will require new guides on such topics as contingency plans, physical security during nonroutine plant operation, records and reports, physical protection, hardware, and quality control. We are closely studying the relationship between physical security of reactor power plants and the reactor system design. Physical protection of special nuclear material in transit is being given highest priority, including such areas as specification of protection systems, operating procedures for communications systems, design specifications for shipping containers and transportation vehicles, and standards for planning response mechanisms and procedures. As you are undoubtedly aware, the generic environmental statement for mixed oxide is due out this summer, with Commission decision on the subject to follow public hearings.

Let me give you my analysis of what I see are the improvements in our standards development process. The NRC, previously under chairman Anders and now under Chairman Rowden, has given the staff very clear guidance and instructions that all standards--those now in place and any new ones issued--must be cost-effective. Accordingly, we have undertaken an assessment of all of our regulatory requirements to assure that they accomplish their safety goals, that they do not impose an undue burden on the regulated industry and consumer, and that they provide a balanced and effective level of regulation. We have clearly concluded that improvements should be made in our standards development program to identify alternative methods of achieving safety goals and to assess the relative effectiveness and comparative impact of all the alternatives. It also seems clear that not only the efficiency but the effectiveness of the regulatory actions can be improved by assuring that the requirements are developed in a framework where both the value and the impact are considered. This can be done without compromising the safety requirements. The climate we are trying to create recognizes that there are usually several ways of accomplishing the same objective and that the procedures should not necessarily be imposed without careful consideration of the potential burden they may create. We are doing this by agressively seeking out information on the impact and value of our proposed regulations and of our existing regulations.

It occurs to me that this Conference and subsequent conferences could provide useful input into our efforts. One thought that comes to mind is that particular topical areas could be assigned to workshops, which could then address the applicability, usefulness, effectiveness, necessity, and completeness or incompleteness of the regulatory base. That information could be used by groups in the standard development and, as a matter of fact, could be given to a particular task leader for his program planning in the coming year.

This approach to obtaining public comment and feedback has given us the benefit of broader insight of the public and the industry, and minimizes the increase in staff resources needed to do the impact assessment. We have identified another area of our standards development in need of improvement; that is the interrelationship among standards. In the past, we have concentrated on the development of the standard on individual topics, with only limited consideration of how these fit together with those in related areas.

The result has been the tendency to establish a safety margin in a piecemeal manner with insufficient attention to possible compounding of conservatisms.

I met with a group last evening and this very subject came up. The subject was emergency protective actions and how they interrelate with the site criteria. There are some obvious discrepancies which need attention. In that regard I might mention that the staff is developing a detailed analysis of our current siting practices, indicating how we got where we are and what the issues and problems are for Commission attention and for further discussion about the need for and the procedures for corrective actions.

The compounding of conservatisms by handling regulations in a piecemeal manner can result in unwarranted capital costs and operating costs which are ultimately borne by the consumer, but they can also result in overdesign in one area, adversely affecting the design margin in another area. We believe that our newly organized approach to carefully evaluate value impacts of new standards as well as existing standards, together with a greater emphasis on developing standards as part of a structured matrix addressing whole technical areas, will lead to a systematic balance which will result in more clearly defined overall safety margins and a more comprehensible and understandable regulatory base.

I would summarize by saying that I think significant progress has been made during the past 3 years in the development of standards which serve to stabilize the regulatory process. The cooperation between the NRC staff and the management of the American National Standards Institute (ANSI) in redirecting the national nuclear standards program has been good. Continuation of the commitment with NRC to make maximum use of that ANSI output in a regulatory program appears warranted.

DISCUSSION

DR. SOLON: Mr. Roberts, in his remarks, made reference to New Reg 0034, which has come to most of you in a green color. I want to make the observation that comments on New Reg 0034 are due 11 days from now, May 17, 1976, at the NRC, and I urge you on Monday after you return to your home base, right after you fill out your travel voucher for this Conference, you immediately turn to the business of New Reg 0034, which will have, if uncontested and not commented on in a serious, the thrust and force of impacting in a very, very serious on your efforts on behalf of public health control--radiological health control--in your jurisdictions. The only other observation is that New Reg 0034, like the first five books of Moses, the Old Testament, and the New Testament, has no identifiable authors. I do ask you to take a look-see at it. If you agree with it, tell the NRC that you agree, but especially if you disagree with it, let the NRC know about it.

MR. HEIDERSDORF: I have a question of the previous speaker. Mr. Blackburn, you made reference to two measurements, I believe you said approximately 25 miles apart; one 70 mR and the other 30 mR. I was wondering what statistical analysis you put this data to show that there is no significant difference.

MR. BLACKBURN: As I indicated, this is preliminary data. Each point was computed by two measurements of about 6 weeks duration. We then calculated the mean of the two exposure values. We did not do any further real statistical evaluation of the significance of the variation. Just to bring up a point, on the surface it looks like a difference of about 13 to 14 mR, about 25 miles apart; as you can see, there was quite a bit of variation in the region. To sort of bring things up to date, is 1 or 2 mR really that significant? If it is, we need to start cordoning off parts of the country and say you can not live there.

WHAT IS GOING ON IN PERSONNEL DOSIMETRY?

Caleb B. Kincaid
Food and Drug Administration
Bureau of Radiological Health

INTRODUCTION

For the past two decades, the U.S. Public Health Service has conducted a personnel monitoring program for its occupationally exposed employees. Over the years the number of individuals monitored has grown from a few hundred to approximately 4000 in 13 different Federal agencies. These people are located in some 237 facilities throughout the continental United States, Alaska, and Puerto Rico. In 1963 the Bureau of Radiological Health, (then the Division of Radiological Health) assumed the responsibility for this program and has administered it since that time.

This report will attempt to describe some of the problems encountered in conducting the program, and will present our approach to their solution. Hopefully our experience can assist others in establishing what we believe will be an improved, reliable, system of personnel monitoring and record maintenance.

DEVELOPMENT OF A STANDARD

Problems in the area of personnel dosimetry have existed since it was first introduced in the early years of radiation protection and later as necessitated by regulatory authorities. These problems range from positive identification of the wearer and the device through the establishment of a generally accepted testing program for insuring the accuracy and reliability of the badges and their readings.

Since the Bureau's involvement in the PHS program in 1963, many efforts have been made by Federal and State agencies to insure the quality of service provided by personnel monitoring suppliers. Added impetus was provided in this direction at the Fifth Annual Meeting of the Conference of State Radiation Control Program Directors in 1973.

One of the recommendations adopted at the meeting was that an impartial Federal agency be designated to direct a continuing performance testing program for suppliers of personnel monitoring dosimeters. A Task Force was established at the time consisting of 15 members from State and Federal agencies to implement the recommendation of the workshop.

One of the decisions of the Task Force was to specify a "baseline performance study" of a representative sample of some 42 commercial suppliers be conducted to determine the "state-of-the-art" in monitoring accuracy and reliability. This baseline study was undertaken by the Bureau of Radiological Health (BRH) through an interagency agreement (IAG) with the National Bureau of Standards (NBS) in 1974. This IAG specified that (1) NBS develop a unified set of methods and criteria for testing the performance of suppliers of film and TLD's for all types of radiation levels encountered; and (2) to evaluate by an essentially "blind test" the performance of at least ten commercial suppliers. After developing the criteria, NBS contracted with Battelle Northwest Laboratories to perform the tests.

A total of nine commercial vendors supplied beta-gamma film badges and five others supplied TLD's. This test was completed in January 1975, and a report prepared entitled "Performance Tests of Commerical Personnel Monitoring Services." Some of the more important findings in this report were (1) the performance of the companies ranged from very poor to good and (2) the American National Standards Institute (ANSI) standards for film were overly complex and had shortcomings, especially with regard to accuracy and performance required or dictated by health physics considerations.

Related to this subject, in February 1974, the Nuclear Regulatory Commission (NRC) decided that it would require its licensees to use dosimeters which had been tested by an approved laboratory using the ANSI standard N13.7 for film and the proposed ANSI standard for TLD's. To evaluate these standards and to discuss the various ways in which the testing laboratory might be established, a Task Force was formed in the Washington, D.C. area consisting of members of interested Federal agencies. Participating agencies include the Nuclear Regulatory Commission, Energy Research & Development Administration, National Bureau of Standards, Environmental Protection Agency, and Bureau of Radiological Health. It was the opinion of the members of this Task Force, based on the results of the BRH/NBS sponsored study of commerical personnel monitoring services, that the ANSI standards could not be used in their present form.

In 1975, the BRH negotiated another interagency agreement with the NBS to develop a standard on "Criteria for Testing Personnel Dosimetry Performance." This agreement has produced a first draft of a standard which is to be reviewed by the Health Physics Society Standards Committee. It is anticipated that this Committee will complete its review and provide comments in June 1976. At the same time the standard will also be provided to the ANSI Main Committee N13 for review and comments.

Upon final approval and publication, ERDA and NRC will adopt this standard for their contractors and licensees. BRH and NBS will promote the voluntary use of this standard for the remainder of the population not affected by NRDC regulations. Future adoption by the Occupational Safety and Health Administration (OSHA) is anticipated. Recently the NRC, ERDA, and BRH have agreed to jointly sponsor a public meeting to be held sometime in September 1976 to inform interested parties of their intent to use this standard and discuss the mechanics involved in instituting the program.

PROBLEM AREAS IN THE PHS PERSONNEL MONITORING PROGRAM

The problems associated with a personnel monitoring program such as the one the BRH administers for the PHS are somewhat unique in that no direct control over approximately 98 percent of the individuals being monitored is possible. This is because of the number of different agencies involved, such as the Indian Health Service, the Bureau of Prisons, and the U.S. Coast Guard, and to the widely scattered geographical locations of the 237 facilities. To complicate this situation, a new contract for badge service has to be prepared and bids requested each year. Some of the resultant problems associated with the above are: communication between the facility and the project officer, long lead times between requests and actions, badges not returned in a reasonable time to the contractor for processing, lost badges, and finally, designation of a responsible person at each facility to administer the program.

Other problem areas identified in this program relate to the commercial suppliers of badges and to contractual specifications. For example. the absence of quality control in the receiving, processing and reading of badges which leads to questions of reliability of reported exposures, proper identification of badges with wearers, and proper indentification of wearing periods. Finally, there are serious questions regarding the definition of terms and units which have been used traditionally in personnel monitoring programs but are not consistent with current nomenclature. These include such items as "dose," "whole body exposure," and "total accumulated occupational dose."

A review of our overall program was initiated in the summer of 1975, when the Bureau was requested to supply some summary and statistical data for publication by the United Nation Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). Based on this review it was decided that many changes were necessary and that more stringent specifications would have to be included in the preparation of a new contract.

CURRENT ACTIVITIES TO IMPROVE THE PROGRAM

A meeting was held in August 1975 with the contractor's representatives to discuss changes in reporting requirements and the establishment of quality control procedures. It was agreed that each month the contractor would supply the Bureau with a magnetic tape containing personnel exposure data reflecting all badges processed during the previous month. In addition, each month the contractor would supply a tape containing all transactions (additions, deletions, and changes) that occurred during the previous month. A change in the immediate notification system for high exposures (600 mrem quarterly, 300 mrem monthly) was agreed upon that requires a Telex message to the facility and to the project officer.

In the area of quality control procedures, changes suggested and agreed upon included: the addition of the first two letters of the person's last name to the record containing the specific badge number to improve individual identification and a modification of the computer program to perform a cross-check of the two letters and three digit badge number to verify that the proper badge number was recorded and keypunched.

A draft of new contract specifications was completed prior to solicitations for bids for a contract for calendar year 1976. A copy of the final version as it appeared in the solicitation is attached as Appendix A.

The revision of our own internal records system to maintain an accurate exposure history file required major changes including combining the data maintained on six magnetic tape volumes into one tape, creating individual history records and recalculating reported exposures on file from raw data supplied by the contractor. This recalculation was necessary due to the contractor reporting a zero for exposures less than the sensitivty of the dosimeter (F20 mrem) and also using a zero for lost or missing badges for the reporting period. In addition, the contractor also reported exposures on late returned badges as occurring during the processing period rather than during the actual wearing period.

This revision in conjunction with the changes initiated by the contractor will enable us to produce standard letters to be sent to any facility not returning badges to the contractor on time and for requesting missing information such as social security numbers, birth dates, and so forth on monitored individuals. More importantly however, from this improved and revised internal records management system we can obtain an accurate exposure history in minutes for any one of the 4,000 individuals on file, and also produce a variety of special listings or statistical data relating exposure to age, occupation, and type of facility.

SUMMARY AND CONCLUSIONS

A complete review of the PHS personnel monitoring program identified many problem areas and the need for improved procedures. Among the most important were the requirements for an acceptable standard to insure the accuracy and reliability of badges and their readings, the revision of external contractual agreements to provide timely and manageable records and the modification of internal manual and automated procedures to increase efficiency and improve effectiveness.

It is anticipated that as a result of an interagency agreement between the Bureau of Radiological Health and National Bureau of Standards a standard testing program will be proposed this year. The details will be presented for discussion at a public meeting cosponsored by the Nuclear Regulatory Commission and the Bureau of Radiological Health in September 1976.

By July 1976 the revised procedures for the PHS personnel monitoring program should be effective with regard to the external service contract and internal records management. A description of the specific methods and activities will be available to interested agencies and facilities at that time.

It is hoped that the basic standard and revised procedures will be accepted by a large number of agencies and facilities utilizing personnel monitoring badges and that the PHS experience will prove useful to others interested in improving their programs.

APPENDIX A

PERSONNEL MONITORING SERVICES CONTRACT SPECIFICATIONS

ESTIMATED VOLUME AND FREQUENCY

The objective of the proposed contract is to provide continuous personnel radiation monitoring service to approximately 4000 Federal employees in 220 installations throughout the United States and Puerto Rico. This service shall consist of supplying thermoluminescent dosimeters in a suitable holder with appropriate identification, hereafter referred to as a "badge", reading the exposed badges worn by the personnel, converting the readings to exposure values, and providing specified hard copy reports and magnetic tape containing detailed data pertinent to the monitored individuals.

Thermoluminescent dosimetry service for personnel radiation monitoring service shall be in accordance with the following:

1. The number of individual badges to be supplied on a quarterly wearing period (13 weeks) to approximately 220 facilities throughout the United States and Puerto Rico is estimated to be on the order of 4000.

2. In addition, a monthly wearing period is required for approximately 300 individuals at facilities desiring monthly rather than quarterly wearing periods.

3. Approximately 600 ring or extremity badges will be required on an annual basis.

4. Under certain conditions a small supply of neutron badges (either film or TLD) must be made available.

5. Badges not returned ninety (90) days after expected receipt, which is 10 days after the wearing period, will be considered lost. The cost for lost or damaged badges will be shown separately on the schedule of prices.

6. At least one control badge shall be supplied to each facility for each wearing period.

TYPE OF THERMOLUMINESCENT DOSIMETER HOLDER OR DEVICE

The thermoluminescent dosimeter shall be of lithium fluoride (LiF) or calcium sulfate: dysprosium ($CASo4:Dy$) composition and shall have a sensitivity equivalent to or greater than the Harshaw Chemical Company TLD 100. The TLD material shall be wrapped or housed in opaque containers to prevent fading from light exposure.

The holder or device containing the thermoluminescent material will contain suitable filters to differentiate between relatively high energy (gamma) and relatively low (beta or low x ray) exposure. A clip or other device for attaching the holder to the garment of the wearer will also be provided.

For identification purposes, each badge will contain facility numbers, wearer's last name and initials, badge number, wearing period, plus a color coding that will facilitate visual confirmation of the period in which the badge should be worn.

DOSIMETER PERFORMANCE CRITERIA

The American National Standards Institute, Inc. "Criteria for Film Badge Performance" (ANSI N-13.7-1972) and the National Sanitation Foundation (NSF) Standard No. 16 "Relating to Dosimetry Sources," revised February 1971, provide performance criteria for personnel monitoring dosimeters. This ANSI standard was promulgated for film dosimeters only, whereas the performance control limits of NSF Standard No. 16, although including TLD's, does not cover the dose range of interest for radiation protection purposes.

In view of the above, bidders must submit evidence that their TLD personnel dosimetry service currently meets performance requirements acceptable for health physics purposes in compliance with NRC regulations and to assess possible health insults to individuals receiving accidental overexposures. The dosimeter performance control limits established by the above standards can be used as guidance on what constitutes "acceptable performance." Data submitted as evidence of "acceptable performance" should include results from an independent testing laboratory. In the absence of results from such a laboratory, other available data or studies indicating achievement of these criteria will be accepted. These data alone or in conjunction with analyses conducted by the BRH will be used to evaluate the contractor's levels of performance. The contractor shall be subject to periodic testing by the Bureau of Radiological Health for compliance with badge requirements as listed in this section.

REPORTING UNITS

Radiation exposure measured from the thermoluminescent material shall be reported in dose equivalent units in accordance with the following table:

Type of radiation	Units taken to be equivalent to 1 rem
X and Gamma	Roentgen
Beta	rad
Mixed	
X + Gamma	Roentgens + Roentgens
Beta + Gamma	rads + Roentgens
Neutron	units as specified in 10 CRF Part 20.4

PROJECT OFFICERS RESPONSIBILITIES

The Project Officer shall notify the contractor of the name and address of each installation requiring monitoring service, frequency of service, the name, social security number, job code, and date of birth of each individual at each installation to be monitored and the date to begin furnishing the service. The contractor shall assign a unique badge number to each specified individual within each facility.

Thermoluminescent Dosimeters in their holders (badges) shall be shipped directly by the Contractor to each installation for which a release against the contract has been given by the Project Officer. Each initial service and all additions to or deletions from the monitoring program will be authorized only by the Project Officer.

BADGE EXCHANGE PERIODS

To provide for continuous monitoring of the covered population, prior to the end of the specified wearing period (monthly or quarterly), the contractor will supply another insert or badge for each individual, plus a control insert or badge for each facility applicable to the next wearing period. These inserts or badges shall be shipped to arrive at the facilities not less than seven (7) days before the end of each calendar quarter, or month, whichever wearing period is applicable. Each participating facility shall be instructed to return exposed badges to the contractor not later than 5 days after the wearing period.

IMMEDIATE NOTIFICATION

Dosages in excess of 600 mrem for quarterly wearing periods and 300 mrem for monthly wearing periods shall be reported immediately to the BRH Project Officer by Telex message (or equivalent). Information to be transmitted shall include individuals name, badge number, social security number, date of birth, facility number, wearing period, and exposure in mrem. The contractor shall also mail a copy of the immediate notification to the facility in which the exposure occurred.

ADDITIONS, DELETIONS, AND CHANGES

The Project Officer will notify the contractor of new personnel to be monitored, personnel to be deleted from the program, and changes in identification of individuals, e.g., social security number and names. Upon notification, the contractor will respond promptly to insure that badges are provided to additional personnel and are not provided for staff deleted from the program. In the case of a quarterly wearing period, when a new personnel badge would not be received by a facility until after the 15th of the last month of a quarter, the new personnel badge will be delayed until the badges for the next quarter are mailed.

RECORDS AND REPORTS

The contractor shall provide, on a monthly basis, Individual Badge Radiation Exposure Reports (see Attachment A) for all badges received for processing during the preceding month. These reports will list the exposure information from badge readings for each facility, and will include the facility name, facility number, facility type, the individual's name, badge number, social security number, job code, date of birth, frequency, and the beginning and ending dates of the actual wearing period of the badge. The exposure information will be identified as to beta or low x ray, gamma or x ray, neutron and part of the body monitored (whole body, extremity, finger). Entries for individuals for whom badges were not received and processed during the month will not be shown on the report. The original and one copy of the report shall be mailed directly to each specified facility and one copy shall be sent to the BRH Project Officer within ten (10) days after the month in which the badges were processed.

The contractor shall also provide the BRH Project Officer with the records of monitored individuals used to generate the monthly report (Attachment A), on magnetic tape in the following format:

(a) Tapes shall be 9 track 800 BPI or 9 track 1600 BPI, compatible with the IBM 370 series computer systems.

(b) Except for "area monitors" and "controls," all identifying fields shall contain entries. A zero will be used only to record a badge reading of "less than 10 mR or less than the lower limits of the sensitivity of the TLD material."

(c) Tapes shall be provided on a monthly basis and shall contain only those individual records for badges that were received and processed during the preceding month.

(d) Each tape record shall include all of the information recorded on the hard copy report.

In addition, a monthly transaction report (Attachment B) shall be submitted to the BRH Project Officer reflecting all additions, deletions, and record correction changes since the previous month's report. In the case of changes, the transaction report shall reflect the old record and the new record after correction.

QUALITY CONTROL OF DATA

Stringent quality control procedures must be maintained on all information collected and produced by the contractor. The contractor shall design and install editing procedures to insure reliability of the data, particularly to insure that the badge being processed is matched with the correct record for the wearer and that readings are assigned to the actual wearing period. Any discrepancy shall be reported immediately to the BRH Project Officer for correction.

DOCUMENTATION

Complete documentation shall be provided to the BRH Project Officer, by the contractor, on all methods and procedures used in collecting, processing, reporting, and quality control of data.

PERIOD OF PERFORMANCE

From January 1, 1976, through December 31, 1976. In order to insure continuity of the program, review of contract performance will be accomplished by the project officer not later than September 15, 1976, and formal notification of the review findings will be made available to all parties concerned prior to October 1, 1976.

DETAILED PRICE STATEMENT

Respondents to the Request for Proposal will provide a detailed price analysis to include, as a minimum, the cost of the individual badge components, reading and converting exposure data, providing required reports and magnetic tapes. Separate price information is also required for monthly and quarterly wearing periods, routine badges, special neutron dosimeters and finger or extremity badges, initial set up charges and special charges associated with lost or damaged badges and additions or deletions from the program. Refer to enclosed Schedule of prices.

CURRENT EVENTS: TRAINING OF STATE RADIOLOGICAL HEALTH PERSONNEL

Charles M. Hardin
National Training Coordinator
Conference of Radiation Control Program Directors

The subject of this report has probably received more comment, review, re-review, criticism, "belly-akin," "copping-out," and "blaming the other guy" than any other recent subject of discussion relating to problems of State radiation control programs.

WHY?

The State program directors recognize the imperative need to have properly trained and qualified personnel to deal with the complicated problems of radiation protection but are frustrated in not being able to fully obtain this training for State personnel.

At the Hyannis meeting, the Executive Committee voted to reduce the National Coordinating Committee to one person--the past chairman of the Conference. In this capacity, the Executive Committee gave me the following charge:

I. To evaluate and assess the total concept of Regional Training Committees and to report these findings to the Executive Committee, and

II. To coordinate the recommendations for potential training needs of the Regional Training Committees at the national level.

Before going into the report, I ask the reader to answer the following questions for himself:

1. Is it imperative that State personnel who protect the public health of the citizens of this country from the unnecessary exposure to radiation be properly trained?
2. If your response to this question was affirmative, who should provide the funding for such training--the Federal government, State government, or both?
3. If adequate funding was available for the necessary training, who should conduct the training--the individual State radiation control programs, the Federal radiation agencies, universities, or other formal training institutions?

In the 1960's, questions 2 and 3 were essentially answered by the Federal government through the provision of training courses for State radiation control personnel by the U.S. Public Health Service and the Atomic Energy Commission. However, in recent years, either because of Federal reorganization, directives from the Office of Management and Budget, agency budget reductions, other agency priorities, and so forth, such Federally funded, Federally sponsored, or Federally conducted courses for State radiation control personnel have been reduced or dropped. The exception to this is the continued excellent training courses funded and sponsored by the Nuclear Regulatory Commission.

In an attempt to "take up the slack" left by the training void, the Conference established the Regional Training Committee (RTC) concept. It is the understanding of the author that the RTC concept means:

> "That State radiation control programs in each specific region (FDA and EPA), in conjunction with the FDA and EPA radiological representatives, will assess their regional training needs, prioritize these needs, and proceed to meet these needs by obtaining or coordinating the actual training courses or workshops within their region."

As a further enhancement of these training needs, each RTC is to provide their prioritized training needs to a national coordinating committee so that identified national needs can be conducted at a national level rather than only at a regional level.

The RTC concept for providing the States' training needs was initiated in 1973. Initially, three pilot regions were chosen and later expanded to all regions except Region IX.

I. Success of RTC Concept

In December 1975, a questionnaire concerning the RTC concept was sent to each State program director, each FDA and EPA regional radiological health representative, and to BRH, EPA, and NRC headquarters. See attachments 1 - 3.

Twenty-eight States from regions with functional RTC's responded. It is interesting that three States in Region IX sent letters regarding their concerns for training, even through they have no RTC. Thirteen FDA or EPA regional radiation representatives responded to the questionnaire. All three Federal headquarter representatives responded.

An overall evaluation of these responses indicate that of the nine regions with functional RTC's, four have been successful, two have had limited success, and three have been generally unsuccessful.

Some States as well as Federal representatives had very strong feelings about the RTC concept both pro and con. The responses ranged from "I feel that the RTC has been quite successful in providing for our training needs" to "other than being talked to death, it has never been given any real care and, as a consequence, has not materialized."

From a total evaluation of the responses, it appears that a simple conclusion as to success of the RTC's cannot be drawn; however, it can clearly be shown that the RTC's in some regions have been very successful while other RTC's have had little to no success.

A. Identified Problems That Cause RTC Difficulties

The one problem over and above all other problems identified as causing difficulties to the success of RTC's is: INADEQUATE FUNDING AT THE STATE LEVEL TO SEND STAFF OUT OF STATE TO TRAINING COURSES.

The above problem was identified by a great majority of the States responding. However, other problems listed included:

ATTACHMENT #1

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS

MEMORANDUM

December 5, 1975

TO: State Radiation Control Programs

FROM: Charles M. Hardin
Past Chairman

SUBJECT: Training Needs

There was hardly a meeting which I attended in the past two years that the subject of training for radiation personnel did not arise. An effort to acquire the training needs for state radiation control programs was initiated with the establishment of Regional Training Committees. Conceptually, the RTC was to evaluate the training needs within its region, to set the priorities of these needs and to coordinate the actual training of radiation personnel. Additionally, a national coordinator was to obtain from the RTC's the training needs and coordinate the appropriate courses at the national level.

The RTC concept has been in operation for several years now and as past chairman of the Conference I have been given the responsibility for totally evaluating this concept to determine if adequate training for radiation control personnel is being accomplished. In light of this responsibility, I would like you to provide me with the following information:

1. Are your training needs being met through the RTC concept?
2. If the RTC concept has been successful in your region why do you think it has been successful?
3. If it has not been successful, what are some of the problems that kept it from working?
4. What is your opinion of other methods that could be used to meet our training needs?

I would appreciate receiving your response to the above questions as well as any other comments you might have that would aid me in evaluating the RTC concept by January 31, 1976.

ATTACHMENT #2

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS

December 5, 1975

As past chairman of the Conference, I have been given the responsibility for coordinating the training needs of the state radiation control programs at the national level. As in the past, my efforts will primarily center around coordinating nationally the training needs that have been established by the Regional Training Committees. In addition to the above responsibility, I have been asked by the Executive Committee to fully evaluate the Regional Training Committee concept. In light of this evaluation responsibility, I would like you to provide me with the following information:

1. Do you feel that the RTC concept has worked in your region? If so, what has caused its success? Has it been successful primarily due to the efforts of the RTC chairman or other state personnel or has it been successful because of your efforts?
2. Do you feel that the training needs of the radiation programs in your region are being fully met? If not, why?
3. Do you believe that the RTC concept is the best method for acquiring the training for our radiation personnel? If not, do you have any suggestions as to how to meet our training needs?
4. When training has been accomplished in your region, who arranged for the training facilities, provided literature and actually performed the instruction?
5. What has been the normal length of training for courses coordinated by the RTC in your region?

I would appreciate your response to the above questions by January 31, 1976. I would also like a listing of all training courses which have been conducted in your region under coordination of the RTC. If there were courses held in the region which were not under the coordination of the RTC, please list these separately.

If you have any other comments that would aid me in the total evaluation of the RTC concept, please include them. I look forward to hearing from you.

Yours very truly,

Charles M. Hardin
Past Chairman

CMH/jpm

ATTACHMENT #3

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS

December 15, 1975

Mr. John D. Vaden
Agreements & Exports Branch
Directorate of Licensing
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear John:

The Executive Committee of the Conference of Radiation Control Program Directors has appointed me as the national coordinator for the training needs of state radiation control programs. I am in the process of obtaining as much information as possible on the availability of various training programs throughout the country. I hope to be able to have a comprehensive report on the total training activities which have been conducted during the last three years and the future needed activities for state radiation control programs.

In my effort to develop this comprehensive report I am sending questionnaires to state Regional Training Committee chairmen, FDA and EPA regional representatives and each state radiation control program director. For purposes of my report I would appreciate receiving from you a list of the specific courses that have been offered to state radiation control program personnel during the last three years as well as courses that are planned for state personnel in the future. Likewise, I would appreciate receiving any other information on training courses in radiation protection that would be appropriate for state personnel of which you are aware that are given by universities or other training institutions.

I realize that my request may require a great deal of effort on your part but feel that the information is necessary to totally evaluate whether the training needs of state radiation control programs are being met. I would appreciate receiving your information on this matter by January 31, 1976.

Your cooperation in this request will be greatly appreciated.

Yours very truly,

Charles M. Hardin
Past Chairman

cc: Sheldon A. Schwartz

1. One observation was "that the RTC's that have an energetic program generally have a chairman who is not a program director who is too busy to give it proper attention."
2. Out-of-State travel restrictions--policy not budget.
3. Too much variation in State needs.
4. RTC meeting held with other meetings.
5. Inadequate time for States to prepare and coordinate quality training courses.
6. The training coordinated by the RTC's are not courses but workshops or seminars.
7. Difficulties in getting a State to host a training course.
8. Too much time spent describing the concept and establishing priorities with little effort spent in actually practicing the concept.
9. Good training can only be done by professional trainers.
10. Lack of Federal support both financially and philosophically.
11. The concept has not been accepted.
12. Too much distance between States.

B. Suggestions for Improved Training

1. The RTC's should be legitimized and made more attractive and useful through some sort of recognition of participation in the form of certificates, continuing education units, and so forth.
2. The Conference could send out "training needs applications." States could then make application for courses needed and then, based on those most needed, BRH, NRC, or EPA could be requested to conduct such courses.
3. Persuade the Federal government to get back into the training business as before.
4. Develop programmed instruction in all phases of training.
5. Develop sound/slide individual learn-at-your-own pace systems.
6. Develop video tape courses which could be made available for loan to States.
7. Develop packaged mini-training courses in specific areas to be conducted by senior State personnel for new employees.
8. Have the Conference obtain training funds through contracts and then subcontract needed courses to professional training institutions.
9. Interchange of ideas and activities between RTC's.

10. Have qualified personnel from one State spend a few days or weeks in another State giving training to the State being visited.

11. Have all interested Federal agencies, the Conference, and the regional nuclear compacts join forces in developing a comprehensive and cooperative RTC-type program on a regional and national basis for direct training to States, built upon solid statutory or established policy with Federal financial support rather than the current "ad hoc" approach.

12. Request the Office of Management and Budget to amend their policy on training and reinstate the courses once provided by BRH.

C. Courses Conducted by RTC's in Past Years by Region

Region I

1. Emergency Response Workshop
2. Advanced Medical X-Ray Protection
3. Emergency Response Workshop (Planned)

Region II

1. Management of Radiation Accidents (Planned)
2. Medical X-Ray Protection
3. DENT Workshop

Region III

1. Transportation Accidents
2. NEXT Workshop
3. Assemblers' Workshop
4. Accident Assessment (Planned)
5. Emergency Planning
6. Advanced X-Ray Techniques
7. Environmental Surveillance

Region IV

1. Environmental Radiation Surveillance
2. Environmental Radiation Sampling Workshop
3. Management of Radiation Accidents
4. Workshop on the Utilization and Interpretation of Environmental Radiation Data (Planned)
5. Basic Radiation Health (Planned)
6. Medical X-Ray (Planned)
7. Management of Radiation Accidents (Planned)

Region V

1. Advanced X-Ray Workshop
2. Emergency Response Training
3. Liquid Waste Disposal Problems
4. Advanced X-Ray Survey Workshop (Planned)
5. Basic Medical X-Ray (Planned)

Region VI

1. Advanced X-Ray Workshop
2. Medical X-Ray Protection
3. Emergency Response Exercise
4. Well Logging for Regulatory Personnel
5. Unretrievable Sources in Gas and Oil Wells
6. Environmental Aspects of Nuclear Power Productions

Region VII

1. Advanced X-Ray Workshop
2. Seminar on Medical Uses of Ionizing Radiation
3. Workshop on Emergency Response Communications
4. Medical X-Ray (Planned)

Region VIII

1. Advanced X-Ray Workshop
2. NEXT Training Course
3. Non-Ionizing Radiation Course
4. Emergency Response Workshop
5. Training Methodology Workshop
6. Medical X-Ray Procedures
7. Radiological Health for Nurses
8. Radiation Safety for Radiologic Technologists
9. Individual Laboratory Training

Region IX

No RTC

Region X

Specific Courses Not Identified

II. IDENTIFIED TRAINING NEEDS

As national coordinator, the following training needs are listed in the order of priority, based on the frequency of identification by the various Regional Training Committees:

Short-Term: 1. Management of radiation accidents with special emphasis on the management of transportation accidents.

2. Program management with emphasis on management by objectives.

The above two courses are the only short-term courses which could be prioritized from a national veiwpoint. Other short-term training needs identified but not frequently enough for the establishment of such on a national basis were (not prioritized):

1. NEXT Workshops
2. Quality Assurance - Sampling
3. Radium
4. Assemblers' Workshop
5. NEXT Data Interpretation
6. Surveillance Around Nuclear Facilities
7. Familiarization in Nonionizing Radiation with Emphasis in Survey Techniques.
8. Specialized Laboratory Procedures
9. Shielding and Design for Teletherapy, Accelerators, Neutrons, and Spontaneous Fission Nuclides
10. Reviewing Environmental Impact Statements
11. Federal Performance Standards
12. Defining the Role of Radioisotope Committees in Small and Large Facilities
13. Nuclear Medicine Technician Training
14. Advanced X-Ray Courses
15. Inspection of Licensees
16. Emergency Response Courses for Fire, Police, and Reaction Teams.

In addition to the above short-term courses, two courses were identified as long-term or courses to be frequently repeated and should be organized on a national basis. These two courses are listed in order of priority:

1. Basic Radiation Protection
2. Medical X-Ray Protection

SUMMARY

In an attempt to evaluate the success of the RTC concept, it was determined that no single conclusion could be reached. The RTC concept has worked well in some regions but has not functioned in other regions. Many varied reasons appear to have caused both the successes and failures. The major reason for success appears to be the result of an energetic RTC State chairman or Federal representative or a combination of both. The major reason for failure appears to be the non-availability of out-of-State travel funds to send staff to established courses.

In identifying training needs at the national level, two short-term courses were identified--Management of Radiation Accidents and Program Management. In addition to these short-term courses, two long-term courses to be repeated were identified--Basic Radiation Protection and Medical X-Ray Protection.

RECOMMENDATIONS

A. Continue RTC Concept

1. The Conference should continue to encourage and support the Regional Training Committee concept in those regions that have had success and which show enthusiasm to continue. To determine which regions are enthusiastic and what type support they desire from the Conference, the Chairman of the Conference should write a letter to each of the Regional Training Committee Chairmen (Attachment 4) soliciting his viewpoint on the continuance of the concept in his region and, if continuance is indicated, requesting him to identify the kind of support he feels the Conference should offer to the Committee.

2. Each Regional Training Committee that desires to continue functioning should meet within the first 3 months after the annual meeting independent of any other meeting. After such meetings, the Chairman should submit their prioritized training needs to the Past Chairman of the Conference who will be responsible for identifying these needs at a national level.

   If travel restrictions would prohibit this type meeting, 1 day should be allocated at the annual meeting for RTC meetings. Since RTC members are mostly Program Directors, the Directors could meet on a regional basis at the annual meeting. If primary "homework" were done, the Directors could prioritize their regional training needs during this 1-day session. Likewise, since all RTC's would be at the same meeting, the Committees could convene during the same day as a group. This total group could then identify their needs from a national viewpoint. Since the various Federal agencies are also in attendance at this annual meeting, a coordinated, solid position could be presented to these agencies with a request for their support.

   The need to have training needs identified, either at the annual meeting or soon thereafter, is so that national needs can be quickly identified. When the Committees meet throughout the year, national needs cannot be identified until the end of the year.

3. When feasible, the RTC Chairman should not be a Program Director but a member of his staff.

4. Each RTC Chairman should be required to summarize their activities and accomplishments on a quarterly basis in a report to the editor of the Conference Newsletter so that RTC's can benefit from each others experiences.

5. Discontinue the National Training Coordinator or Committee since national needs will be identified by the Past Chairman.

6. The Conference should consider formalizing courses coordinated by RTC's. A suggested workshop for the next annual meeting would be to develop minimum criteria for courses to be formally recognized by the Conference. When courses meet these criteria, the Conference should issue certificates of recognition to the participants.

7. For those courses recognized as national needs, the Conference should consider acquiring training funds from Federal agencies or other institutions for the conduct of such courses. When such funds became available the Conference could subcontract the training to appropriate professional training institutions.

ATTACHMENT #4

1976 REGIONAL TRAINING COMMITTEE CHAIRMEN

Region 1 Jack Stanton - New Hampshire
Region 2 Lawrence Czech - New York
Region 3 Beattie DeBord - West Virginia
Region 4 Bill Graham - Tennessee
Region 5 Don Vanfarowe - Michigan
Region 6 Dale McHard - Oklahoma
Region 7 Ken Miller - Missouri
Region 8 Melvin Nelson - South Dakota
Region 10 Archie Gore - Washington

B. Training Outside RTC

1. Since out-of-State travel budgets are limited, other type training within the State or local radiation control program must be obtained. The following recommendations are made in this area:

   a. The Conference must obtain certain routine courses in pre-packaged form that can be acquired by individual State or local radiation control programs. These pre-packaged training courses should provide for self-training by the staff. Senior staff members could use these pre-packaged courses to instruct junior or new staff members. These pre-packaged courses should contain:

      (1) Viedo tapes to demonstrate dynamic or action procedures such as survey techniques

      (2) Instructional materials with questions and answers for self-instruction

      (3) Slides which show non-dynamic or no action such as bio-effects, interaction of radiation, etc.

   These type courses could be sectionalized into Basic, Medical X-Ray Protection, Advanced X-Ray, and so forth. It should be noted that the Bureau of Radiological Health is in the process of developing some of these pre-packaged courses.

   b. To obtain the pre-packaged courses referenced above, the Conference should:

      (1) Submit letters of request for such courses to each of the supporting Federal agencies,

      (2) Seek funds to contract with professional instructional institutions to develop such courses, and

      (3) Consider appointing a task force to develop such pre-packaged courses from existing training materials and make such available directly through the Conference.

C. Re-Evaluate Priorities Placed on Training

Since it appears that funding for State training at the Federal level will not become available in the near future, a State must do some "soul searching" as to the priority it places on having adequately trained personnel.

If the needs are as great as most States indicate on the one hand and yet on the other hand funds cannot be obtained to pay for training when it is available, an unusual paradox exists. Either the needs are not as great as professed or those persons within a State responsible for budgeting have not been convinced of these needs.

If the training of State radiation protection personnel is given adequate priority in budget preparations, the above paradox should cease to exist. If it can then be shown that States have funds for training, more training in professional training institutions may become available.

D. Available Courses During the Year

For courses in radiation protection or those related to radiation protection, see Attachment 5.

RECENT COURSES RELATED TO RADIATION PROTECTION

Attachment #5

(For Address & Phone No., Note Code Number @ end of Sponsor)

	Type Course	Length	Dates	Cost	Sponsor
A.	Basic Rad Health	2 weeks	1/5 - 16/76	$200/wk.	Lowell Technological Institute (1)
	Basic Rad Health	2 weeks	3/22 - 4/2/76	$525	Georgia Institute of Technology (9)
	Basic Rad Health	1 week			Harvard University (10)
B.	Basic Health Physics	4 weeks	5/17 - 6/11/76	$200/wk.	Lowell Technological Institute (1)
	Basic Health Physics	10 weeks		$2500*	Oak Ridge Associated Universities (6)
	Basic Health Physics	2 weeks	5/3 - 14/76	$735	Rockwell International (14)
C.	Program Management	1 week		$125 to $250	Atlanta Regional Training Center (2)
	Program Management	1 week	5/17 - 21/76	*	U.S.N.R.C. (7)
D.	Radiation Protection Surveys	2 weeks		$500	University of Michigan (3)
E.	Respiratory Protection	4 days	2/17 - 20/76 3/22 - 25/76 4/20 - 23/76 6/8 - 11/76	$250	N.I.O.S.H. (15)
F.	Non-Ionizing Radiation				Georgia Institute of Technology (4)
	Non-Ionizing Radiation	3 days		$200	N.I.O.S.H. (5)
G.	Introduction to Lasers	1 week			University of Cincinnati (13)
H.	Laser Safety	1 week			University of Cincinnati (13)
I.	Ionizing Radiation	1 week		$300	N.I.O.S.H. (5)
J.	Medical X-Ray Protection				U.S. Army (8)
K.	Radiopharmaceutical Dosimetry	4 days		$40	Oak Ridge Associated Universities (6)

Attachment #5 (continued)

Type Course	Length	Cost	Sponsor
L. Management of Radiation Accidents			
a. Health Physics in Radiation Accidents	2 weeks		O.R.A.U. (6)
b. Handling of Radiation Accidents by Paramedical Personnel	1 week		O.R.A.U. (6)
M. Radiation Emergency Planning			
a. Medical Planning & Care	1 week		O.R.A.U. (6)
Radiation Emergency Planning	1 week	$425	Harvard University (10)
Radiation Emergency Planning	1 week	*	U.S.N.R.C.
N. Medical Use of Radionuclides for State Personnel	1 week	*	U.S.N.R.C. (7)
O. Safety Aspects of Industrial Radiography for State Personnel	1 week	*	U.S.N.R.C. (7)
P. Orientation Course in Regulatory Practices & Procedures	1 to 2 weeks	*	U.S.N.R.C. (7)
Q. Inspection Procedures	1 week	*	U.S.N.R.C. (7)
R. Gas & Oil Logging for Regulatory Personnel	1 week	*	U.S.N.R.C. (7) and State of Texas (12)
S. Environmental Radiation Surveillance for Nuclear Power	1 week	$425	Harvard University (10)

* For state regulatory personnel, NRC will pay all cost of training course.

Attachment #5

Name and Address of Sponsors

1. Kenneth W. Skrable, Ph.D.
Radiological Sciences Department
Lowell Technological Institute
Lowell, Massachusetts 01854
(617) 454-7811 Ext. 234

2. Atlanta Regional Training Center
U.S. Civil Service Commission
1340 Spring Street, NW.
Atlanta, Georgia 30309
(404) 526-3837

3. G. Hoyt Whipple
School of Public Health
The University of Michigan
Ann Arbor, Michigan 48109
(313) 764-0523

4. Karl Z. Morgan, Ph.D.
School of Nuclear Engineering
Georgia Institute of Technology
Atlanta, Georgia 30332

5. Chief, Environmental Management Br.
National Institute for Occupational Safety and Health
Division of Training
9503 Federal Office Building
Cincinnati, Ohio 45202
(513) 684-3252

6. R. J. Cloutier, Chairman
Special Training Division
Oak Ridge Associated Universities
P.O. Box 117
Oak Ridge, Tennessee 37830
(615) 483-8411, Ext. 263

7. John Vaden
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

8. U.S. Army
Unknown

9. Dr. Melvin W. Carter
Office of Interdisciplinary Programs
Georgia Institute of Technology
Atlanta, Georgia 30332
(404) 894-2375

10. Department of Environmental Health Sciences
Harvard School of Public Health
665 Huntington Avenue
Boston, Massachusetts 02115

11. Office of International and State Programs
Nuclear Regulatory Commission
Washington, D.C. 20555

12. David K. Lacker, Administrator
Radiation Control Branch
Texas Department of Health Resources
1100 West 49th Street
Austin, Texas 78756
(512) 454-3781

13. University of Cincinnati
Burnet Woods Campus
Cincinnati, Ohio 45221
(513) 475-8000

14. Rockwell International
Atomies International Division
8900 De Soto Avenue
Canoga Park, California 91304
(213) 341-1000

15. Robert A. Taft Laboratories
National Institute for Occupational Safety and Health
Division of Training and Manpower Development
4676 Columbia Parkway
Cincinnati, Ohio 45226
(513) 684-8225

CURRENT EVENTS: THE KERR-MCGEE INCIDENT

Robert L. Craig
Radiation Protection Division
Oklahoma Department of Health

I found out about the fact that I was supposed to be up here about 30 minutes ago to speak about Karen Silkwood, but this is no real problem, aside from the fact that I do not have a written statement, because the name is burned indelibly into my brain and so are the facts of the case.

I would like to discuss very briefly some of the facts and stay away from the speculations, because the number of speculations are astronomical and you still could not come up with all of them. Very briefly, the facts.

One day we received a call from Kerr-McGee saying that there was extensive plutonium contamination in an apartment in one of the suburbs of Oklahoma City. You can imagine what sort of a flap this caused around the office; all hands and the cook responded. Nevertheless, we did find that the report was true; there was extensive contamination. The major sources, or spots, and the hot spots were just that; they were very hot; they were small spots.

Inside the apartment, there was extensive contamination, with a few very hot spots, up to 400,000 dpm per 100 square centimeters on a piece of bologna in the refrigerator. The second highest spot of contamination was somewhat less than this, but it happened to be on the toilet seat in the bathroom; confusing to say the least.

The total amount of material involved, as nearly as can be determined, was 0.3 milligram of plutonium oxide; not very much, but it caused one fantastic flap. Every meeting I go to, I still get questions about it.

Karen Silkwood had been involved very shortly prior to the incident in question in numerous incidents of contamination of her person inside the plant. We found out that the night previous to the discovery of the contamination, Ms Silkwood had been slightly contaminated in the plant and had undergone extensive decontamination procedures and was clean when she left. However, the next morning, on returning to work, she again went through the survey procedures, and was found to be contaminated, and, of course, this raised some questions. This was the initial indication that there might be contamination offsite.

Shortly after the incident (within a week), Ms Silkwood was killed in an automobile accident. She had attended a meeting in a small town about 7 miles north of the scene of the accident. She was driving alone. Her automobile left the highway and drove down the ditch for several hundred feet and ran into the wing abutment on a culvert. The significant part of this accident was that there were absolutely no skid marks, no apparent attempt from the tire marks in the grass and dirt that would indicate that any attempt whatever had been made to avoid the concrete abutment, either to pull back on to the road or out through a fence into an open field. At autopsy, it was determined that she was under the influence of methaquanone, a hypnotic sedative drug.

Between the time of the initial discovery and her death, she had been on a bioassay program and there was plutonium found in both the urine and fecal specimens; the exact numbers are available in the official documents, which are in the NRC open files. The one I am most familiar with is in the public library in Guthrie, Oklahoma. I am sure that there are others at NRC headquarters. If you want more details of specific numbers, they are available to you.

Suffice it to say that the pattern of plutonium found in the biological specimens did not make sense. The only thoroughly supervised specimens were obtained at Los Alamos, where she was sent for whole body counting. After her death, a team of specialists from Los Alamos took the standard plutonium autopsy specimens. The best estimate of her total body burden, estimated from autopsy specimens, was something on the order of--I can't be specific. It was very low; a fraction of a maximum permissible body burden.

I interviewed this young lady twice prior to her death, and we could not elicit any really substantive information from her.

The apartment was decontaminated to the bare walls. All of the furniture was removed; even the paint from the walls. The question has arisen in many instances, why such extensive decontamination? The NRC was very active in this incident, as were we, and we had agreed that the NRC guidelines would be sufficient. As I recall, it is something like 100 dpm per 100 square centimeters of removable alpha. Everyone agreed that decontamination to these limits would be adequate. Kerr-McGee elected, on their own, to go to 0 detectable activity, and this was the extent to which the apartment was decontaminated. This meant that they took everything that was moveable from the apartment and, in some cases, the paint from the walls. The final check on the adequacy of the decontamination was done by Coleman Smith, and those of you who know Coleman know that he is an extremely thorough gentleman.

The last of the contaminated articles in the apartment was found to be the plastic cover over the doorbell, which had 31 dpm per 100 square centimeters on the back side of it. We know that there is nothing left in the apartment; it has been cleaned up.

This incident still has many, many questions that have never been answered, and will never be answered, but the interest continues to be high. I know I have left some questions in your minds; they will just have to stay there, because I still have the same questions.

CURRENT EVENTS: TRANSPORTATION OF RADIOACTIVE MATERIALS

Andrew P. Hull
Safety and Environmental Protection Division
Brookhaven National Laboratory
Upton, New York

I think that most of you are aware that back about last November, the City of New York proposed some regulations within their health code having to do with the transportation of radioactive materials through the city. These regulations essentially prohibited, except under a certificate of emergency, the transportation of Class B type shipments through the city. The final approval, I think, softened this a little bit in regard to large sources used for medical purposes. The upshot was that, since New York City is on the straightest line between Brookhaven out on Long Island and Savannah River, where our spent fuel was shipped for reprocessing, the straightest line by land was no longer available. EDRA, as soon as this was passed, went to court to seek an injunction against this de facto prohibition. The injunction was not granted, but the matter is in the courts, and I presume that in due time it will be heard. This may be a long drawn out process. Meanwhile, the Laboratory is under some pressure to transport fuel, and a couple of shipments were made via the Orient Point Ferry and through Connecticut, in a roundabout route.

I am with you today, as I have been in a number of conferences, really for a meeting of the APHA Radiological Health Section. I have always wished that I had more time to attend the Conference, because it looks like the most interesting meeting on radiation protection of the year for someone who is in the operating side of radiation protection and health physics. When he learned that I was to be here, our Division head, Charles Meinhold, suggested that I say something about the transportation issue. Unfortunately, pressed by other matters, he never told me what he wanted me to say, so I am not quite sure what I should say. I think he wanted me to give you a quick rundown on what was in NUREG 0034, and I don't think I am about to do that, even if I had the time. We had a session on it at the Laboratory a couple of weeks ago--an information session--and it was a couple of hours of presentation of just the high spots of it. I had scanned it at that time and I have run through it since. I certainly think that those of you who are more directly involved will certainly want to read it to assess it for yourself. I am impressed, not knowing that much about the overall picture before I picked the document up, that with regard to routine shipments, most of the exposure comes from radiopharmaceuticals, and a lot of that by air transportation. Only about 2 percent of the exposure seems to come from spent fuel, which seems to be the principal agrument or controversy as far as transportation is concerned.

It also has a section on the assessment of accidents, and the principal potential dose from accidents is from plutonium itself, which initiated controversy initially. Perhaps more will be said about that tomorrow.

The end result, when you get down to the relative risk, if you put all of this together, using the BEIR Report numbers, and extrapolations, and all of that, as modified by the appendix in the Rasmussen Report--the numbers range from the individual risk of fetal injury per year of motor vehicles of 1 in 4,000; electrocution is 1 in 160,000; the Rasmussen integrated risk from reactor incidents is 1 in 5,000,000; whereas the risk associated with the shipment of radioactive materials is 1 in 10^{15}. One wonders what all the excitement is about in transportation in view of the infinitesimal risk.

Well, that is the objective side, insofar as I can speak officially as to what the Brookhaven position is. I will now to wear another hat which says that as the Public Information Chairman of the Health Physics Society, we had a conference about a month ago, and I think it was a consciousness raising session for health physicists, including myself. We had invited several of the outstanding nuclear critics to be there. I was suprised that there was very little argument on this occasion about the objective facts that we hear so much about; numbers and risk assessments. Most of their concern over nuclear power (and I am assuming that this transportation regulation is tied in with nuclear power), had more to do with value judgments. Bill Rowe of EPA said that in risk assessment, death is the one certainty in life, and the only question is when, where, how, and is it final. Then, of course, everybody laughed. And then he said, this has to do with values; it only matters to people how they look at that. I think we are into a value area here, as I see what is going on. People who pose these value judgment reservations about nuclear, for whatever ulterior reasons that do not have much to do with safety, have been looking for the achilles heel, the weak spot that will get a lot of headlines and create a public atmosphere of distrust in nuclear power. This is the latest place that they find it. I must sympathize with those of you who are out there on the firing line. What do you do? It was pointed out to us at the Health Physics Conference that it is not what we, who tend to look at objective facts, believe or how we assess things, it is what the public believes the risk is that constitutes how they are going to look at things. In your positions, I think you have to somehow address yourself to this.

DISCUSSION

DR. SOLON: Just one observation, with respect to the transportation regulation of the City of New York being antinuclear; it is in no sense antinuclear. If you have one consequential transportation accident in a large urban area, and public pressure and public trust will close down the nuclear industry. The fact of the matter is, the only way that nuclear power is going to be sustained on a sound public basis, is if the very vulnerable public transportation link is given the right kind of regulation and the right of scope, which it has not. So this identifying an effort in behalf of public health, good radiological health control, as antinuclear is pejorative. Dialogue will reveal the problem, which conferences such as this can never address itself to.

DR. HULL: I guess we are into an agrument about priorities and expenditure of money and efforts, and what really constitutes "as low as practicable." Obviously, there are irrational factors in the New York scene which we need to address. New York City does not really solely control everything that goes through there. There are independent bridge and tunnel authorties with their own rules, so one could not take a straight line through New York City with hazardous shipments, even if one wanted to. Thus "as low as practicable" routings are very difficult, due to these various independent authorities. Our response is that radioactive waste shipments are not very vulnerable. If you are going to be really very honest and objective about worrying about these things, then there are a lot of other hazardous agents which move through the city every day, and which are far more vulnerable, or could do far more damage. The nuclear risk is awfully far down the list of where you would presumably spend your money, time, and effort to protect the public. Of course, there is something to what Dr. Solon is saying, if you go back to this confidence-credibility factor. Certainly it has to be dealt with, since it is the lastest achilles heel.

DR. SOLON: The driving force behind this regulation was the Board of Health of the City of New York, which in no sense is antinuclear. Let me just conclude that by making the observation that the document 0034 came without making any pronouncements on its merits or the structure of the model. It deserves your very careful reading and your very careful comments, but by May 17, 1976, your comments must be received by NRC.

CURRENT EVENTS: STATUS REPORT ON EMERGENCY PREPAREDNESS

Harold E. Collins
Office of State Programs
U.S. Nuclear Regulatory Commission

Every year, I wind up here by hook or by crook with some kind of a status report on our activities in the emergency preparedness effort. Sometimes I feel like a broken record on many of these aspects of our program, but nevertheless we do seem to be making some progress in many areas, but in other areas, of course, we are not making the progress we should be making.

First of all, I would like to remind all of you, if you haven't noticed it, that on December 24, 1975, the Federal Preparedness Agency, General Services Administration, did revise the notice of interagency responsibilities for the Federal interagency assistance program to the States in radiological emergency response preparedness. That was published in the FEDERAL REGISTER on that date.

Some significant changes in the notice; instead of five agencies having responsibilities, there are now eight. The reason for that was, of course, the split of the AEC into ERDA and NRC. The NRC is the lead agency in this program and DOT, ERDA, HEW (specifically FDA/BRH and the Emergency Medical Services portion of the Public Health Service in HEW), EPA, the Federal Preparedness Agency itself, the Federal Disaster Assistance Administration, and the Defense Civil Preparedness Agency all have responsibilities under the provisions of this notice.

Significant change in the new Notice as compared to the old Notice is, for the the first time the Notice does levy upon the Federal interagency group the responsibility for providing training to State and local government personnel. The aspects of the training are not spelled out. The training is considered to be that training which is related to the overall radiological emergency response preparedness effort. So this is the significiant departure from the old Notice, which did not even mention the word training, although we had, even under the provisions of the old Notice, gotten into the training business.

The Notice, of course, keeps us in the guidance and assistance effort. We like to interpret that as a field assistance effort.

With respect to training, I suppose that is probably going to be our biggest effort during the next fiscal year. We are pretty well winding up the Battle Creek course in planning now. We have trained over 300 State and local government emergency response personnel, and I use that word "trained" advisedly; at least they have attended the course, and they have been exposed to what was presented at the course. What they got out of it, I guess, was what they put into it, or what they perceived they could get out of it. The course has met with mixed reaction; some people think it is a very good course, others don't think it is worth a damn; but, that is to be expected, because when you develop a course like that, if you get comments that put you right down the middle, you figure that is about as good as you are going to do, anyway. We are pretty pleased with the course. I think most State people, and certainly local government personnel, are pleased that the effort was made. We have conducted the course eight times, and I believe the ninth time was in Austin, Texas last week. The course mainly has been conducted at the Defense Civil Preparedness Agency Staff College at Battle Creek, but it has been on the road four times, also. The next course will be in Denver for the Western States that are east of the Rocky Mountains. At that time it will have resulted in the exposure of personnel in all 48 contiguous States to the concepts of this course. There will be two more catchup sessions in June, probably in Battle Creek, and then in September at Battle Creek. We are giving the States and local governments an opportunity to send those personnel to these courses who did not have the opportunity to attend one of the others for a variety of reasons. After that, we probably will run the course about once a year, or on demand from the various States and local governments. But we envision probably once or twice a year for the course in planning.

We have a lot of other training activities under development. We are working with ERDA and the Reynolds Electric Company in Las Vegas, Nevada, which is an EDRA test site manager. ERDA is asking Reynolds for a complete cost breakdown for training about 2,000 State and local government personnel in a course entitled "Radiological Emergency Response Operations." The curriculum for the course has been developed. There were Conference of State Radiation Control Program Directors representatives on the curriculum development effort, as well as Federal and local government people, civil defense, and so forth. It was about a 12-person group that developed and improved the Reynolds curriculum. I think Reynolds is very happy with the improved curriculum, and we think that it will offer a pretty good course that will meet both NRC's and the State and local government needs as well as ERDA's needs. EDRA has a need for this course as well for their own people, and we would like to combine the effort. It will be a very expensive course to run. Cost estimates run as high as $350 to $400 a week per student. We are going to try to Federally fund the entire thing, and try to get 2,000 radiological monitoring personnel through that course in a few years. I do not know how long it is going to take. A lot depends on what kind of a load Reynolds is able to handle. It will be either a 1- or a 2-week course, depending on the background of the individual; if the individual has a fairly good background in radiological monitoring practices or health physics, he would go to the 1-week course. This involves a lot of field exercises in monitoring and accident assessment. If he does not have a very good background, but has a need to know, as perceived by his community or his organization, then he will get the full 2-week treatment. The first week consists of a lot of basics of health physics.

The Environmental Protection Agency has run a pilot course for Radiological Emergency Response Coordinators in Charlottesville, Virginia. Some of you attended that course. It was the first effort to put a course together for State radiation control program directors, or people who have the primary responsibility in the States for advising the Governor in the event of a radiological emergency what to do in the event of a serious radiological incident in that State. The course was evaluated. We have not received the evaluation yet from EPA. EPA is the lead agency in this particular course.

We did send a group of people down to Oak Ridge National Laboratory to take a look at the paramedical course for radiological personnel, and we found that course to be of great interest and potential value, but a lot of difficulties with it. One of the significant things that we noticed concerned the faculty for the course: there were no nurses on the faculty, nor were there any paramedical personnel on the faculty. That kind of tells you something about the course. The faculty was largely medical doctors; a lot of big names in nuclear medicine, of course, and also several of Oak Ridge's health physics personnel. But the course does have potential, but it needs reorientation. We hope to be able to submit a report on that paramedical course, which was the first one that Oak Ridge ran. It is a 1-week course, and hopefully, through ERDA, get Oak Ridge to make the necessary changes. We would like to be able to make that course available to State and local government people on a fully funded basis. We will be putting out some information on these courses that are under development as we get them developed and as we beat the drums among our Federal peers for money to support them.

The Federal Preparedness Agency's Federal Response Plan of Peacetime Nuclear Emergencies, that you have all heard about is in draft form. It is being reviewed by the Federal interagency group. Probably the Federal Preparedness Agency will publish, or send our for formal comment, the Federal Response Plan of Peacetime Nuclear Energencies this month. I was informed by Marshall Sanders of the FPA that he will be sending the Plan and its Annex, which was developed by a consultant corporation (the Annex is entitled "Guidelines for Federal/State Relaltionships for Peacetime Nuclear Emergencies"), to the Conference of State Radiation Control ·Program Directors Chairman for comments by the Conference. That will probably will be done within the next month. Your Chairmen-Elect will be involved with the FPA on that matter, I am sure.

Last year, you did have a Workshop No. 6, and you came up with a number of recommendations; four of which applied to the Federal agencies, one applied to the States, and the sixth applied to both. The last one concerned providing Conference liaison representation on the Interagency task forces on training and exercises. We do have a liaison representative, Margaret Reilly, who has attended all the training task force meetings since she was appointed last fall. I understand from Bob Will that the appointment of additional members to our other task forces will probably be taken up by your Conference before you adjourn on Friday. We do solicit more liaison representatives to be assigned to these task forces.

Another major comment concerned recommendations to the NRC to review 10 CFR 100, Siting Criteria Regulations, and its relationship to EPA Protective Action Guides and Emergency Planning. I will not elaborate on that, other than to say that Craig Roberts and Ed Held from NRC Office of Standards Development, who spoke to you this morning, have that sack in their office. A paper is being prepared for the Commission, which will outline a number of things related to 10 CFR 100. We had a little ad hoc session yesterday between Craig Roberts, Ed Held, Aubrey Godwin, Maggie Reilly, Alice Dolezal, Sherwood Davies, and Marshall Parrott, so that some State people, at least had a chance to talk to Craig and Ed to get some indication of their concerns with regard to the siting criteria and how that overlaps with emergency preparedness and EPA Protective Action Guides.

Another recommendation concerned the ACRS letter. All I can say on that is that I do not have the ACRS letter with me--the one that Kerr wrote to Anders--but your Conference recommended that the Commission get off its duff and start addressing all these matters. We did write a letter to the ACRS, and we have activity going on in each one of those areas. We intend to try to submit a report to the Conference, probably some time this summer on all of those activities in a more detailed fashion. You wrote to us about all of this in November, and we have not responded to your recommendations officially, yet.

Another recommendation concerned Federal tardiness on providing more complete, full-scope PAG's, accident scenarios to test field exercises, and thyroid blocking policy. We do have a contract with Sandia Laboratory to develop accident scenarios to test emergency plans, and all I can say about food PAG's and thyroid blocking is write to FDA, BRH and see what you can do to get them to move. Every letter that we have gotten from the States--from Oregon, Kansas, and so forth--which concern this matter of FDA/BRH's guidelines in thyroid blocking, have been transmitted to Bernie Schleien in BRH. I would suggest that you write to Bernie.

Funding of emergency planning activities; that is talked about in the GAO report. We are making some recommendations concerning that to the Commission. That is about all I would like to say on that at this time.

In closing, I would like to say that we do not have all the answers in this business, and we realize that there are a lot of problems in the emergency planning business. One thing I would like to emphasize is that as we get smarter in this thing, we are going to become more confident in it. I want to urge all of you to exert comparable efforts in your areas in order to achieve a better response posture around the country, because even though we do not have all the answers, there is a certain amount of the sack that is dumped on your doorstep, and you have to help us lift it. We cannot lift it alone. I was very heartened to hear some statements made here over the past few days that indicate that the States are taking charge in some areas, despite the lack of Federal guidance. I just want to encourage you to do that, because otherwise, if we sit around and wait for all the stuff that everybody wants to have, we will never improve our radiological emergency response posture. I urge all of you to exert whatever comparable effort you can, in addition to what the Feds are doing, to try to improve the overall posture of the Nation with regard to radiological emergency response preparedness, in support of fixed nuclear facilities, and for other things as well.

SESSION: MOVING ON

Moderator: *J. Dale McHard*, Oklahoma

STATE OF CURRENT AND PROPOSED REGULATIONS AND LEGISLATION FOR TRANSPORT OF RADIOACTIVE MATERIALS
Alfred W. Grella, Materials Transport Bureau, U.S. Department of Transportation

PUBLIC HEALTH ASPECTS OF TRANSPORTATION OF RADIOACTIVE MATERIALS IN LARGE URBAN AREAS
Dr. Leonard R. Solon, Director, Bureau of Radiological Control, New York City Department of Health

TRANSPORTATION OF RADIOACTIVE MATERIAL IN ILLINOIS
Philip N. Brunner, Chief, Division of Radiological Health, Illinois Department of Public Health

PANEL: STATE EXPERIENCE IN HAVING AN OSHA AGREEMENT
Robert H. Wolle, Director, Division of Occupational and Radiological Health, Tennessee Department of Public Health
John R. Froines, Ph.D., Director, Division of Occupational Health, Vermont Department of Health

CLOSING SESSION

Moderator: *Gerald S. Parker*, Massachusetts

WORKSHOP SUMMARY REPORTS

Workshop No. 1 - Guidelines for Surface Contamination Limits Applicable to Unrestricted Use by the General Public (Exclusive of Land Surfaces)
Sherwood Davies, Chairman, New York

Workshop No. 2 - Guidelines on Surveying a Medical Accelerator
Edgar D. Bailey, Chairman, Texas

Workshop No. 3 - Methods for Achieving Support for Your State Radiation Control Program Budget
Aubrey Godwin, Chairman, Alabama

Workshop No. 4 - Establishment of Soil Contamination Limits
A. J. Hazel, Chairman, Colorado

Workshop No. 5 - Review and Evaluate the Need for and Content of Annual State Radiation Control Program Reports
Donald E. Van Farowe, Chairman, Michigan

Workshop No. 6 - State/Federal Relationship for Enforcement of P.L. 90-602
Richard Lane, Chairman, District of Columbia

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Workshop No. 7 - Information Needed to Evaluate Public Health Impact of Nuclear Medicine Practice
Gerald W. Allen, Chairman, Kansas

Workshop No. 8 - State Credentialing Program for Radiation Allied Health Operators
Larry L. Lloyd, Chairman, Montana

REPORT ON RESOLUTIONS
Gerald S. Parker, Chairman, Massachusetts

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS EXECUTIVE COMMITTEE REPORT
Gerald S. Parker, Chairman, Massachusetts

SUMMATION AND CLOSING REMARKS
Gerald S. Parker, Chairman, Conference of Radiation Control Program Directors, Massachusettts
Sheldon A. Schwartz, U.S. Nuclear Regulatory Commission
Robertson J. Augustine, Ph.D., Environmental Protection Agency
James W. Miller, D.D.S., Radiation Operations Staff, Division of Field Operations, Executive Director of Regional Operations, FDA

STATE OF CURRENT AND PROPOSED REGULATIONS AND LEGISLATION FOR TRANSPORT OF RADIOACTIVE MATERIALS

Alfred W. Grella
Materials Transportation Bureau
U.S. Department of Transportation

I appreciate very much this opportunity and privilege to take part in this very important Conference. I am also especially pleased to be able to represent the U.S. Department of Transportation here for the first time.

My presentation this morning is intended to provide you with an update of the regulatory and legislative situation with respect to the safe transportation of radioactive materials.

As it relates to the theme for this conference, i.e., "Radiation Benefits and Risks: Facts, Issues and Options," the transportation of nuclear materials represents a very timely topic for discussion. I would point out that, as has been the case for all nuclear matters generally throughout the public domain in the past several years things can be characterized as having been quite hectic, at least with respect to the public relations, public awareness and acceptance, and emotionalism aspects. Many of you are probably aware of the wide publicity and media coverage which has been given to most transportation "events" in recent months. You may also be aware of such things as the railroads' recently adopted position on carriage of spent fuel and the current action on this within the Interstate Commerce Commission. The actions by several States and local jurisdictions in adopting very restrictive rules on transport of nuclear materials have also come to the forefront. Also, the Congress has been somewhat restive on certain transportation issues, resulting in some recent legislation on such issues.

In September 1974, I had the privilege of delivering a paper at the Fourth International Symposium on Packagingand Transportation of Radioactive Material in Miami, Florida. The title of that paper was "An Update on the Status of Recent and Proposed Changes to the U.S. Regulations for Transport of Radioactive Materials" (1). Since it covered the status of regulatory changes during the period 1972 - 1974, I shall generally base my results today from 1974 as a starting point, taking us right up to the present time.

The various regulatory amendments, proposals, or legislation include:

1. Miscellaneous Changes Relating to Radioactive Materials, Docket No. HM-111 (2).

   A major regulatory docket concerning radioactive materials was issued by the Department as a notice of proposed rulemaking in Docket HM-111, on October 25, 1973, under the caption: "Miscellaneous Proposals Relating to Radioactive Materials." In this proposed notice, a number of amendments, based on experience since the major regulatory revision of January (HM-2) were proposed. These proposals were published as final amendments on December 31, 1974 (3), among the changes therein were the following:

   a. Packages containing liquid radioactive materials exceeding Type A quantities are now required to meet both the 30-foot drop test and the liquid absorbent provision or a requirement for doubly-sealed inner containment.

b. The method of listing "families" of certain packagings as authorized Type A packagings has been deleted. In their place, reference is now made to only the DOT Spec. 7A, Type A general performance specification, with an added requirement imposed, however, that any user of Spec. 7A packaging is required to document and maintain on file a record of his determination of packaging compliance.

c. Newly constructed DOT Spec. 55 packagings are no longer authorized for shipments of limited Type B quantities (20 curies to 300 curies) of special form radioactive materials.

d. Changes to the design requirements, as well as the authorized fissile radioactive contents of the DOT Specifications 6L and 6M packagings were promulgated.

e. Design modifications to the DOT Spec. 2R inner containment vessel (a component of both the DOT 6L and 6M) were made, providing more definitive requirements for flanged closures.

f. Several new DOT specification packagings were published to replace several widely used special permit packages; i.e., DOT SP 4609 (UF^6 in protective overpacks), DOT SP 5800 (Spec. 55/wooden overcoat), DOT SP 5725 ("Sugarman" Spec. 55/wooden overcoat), and DOT SP 5021 (fissile uranium-235 loadings in steel drums), and DOT SP 6273 (fissile F_6 "heels" in bare cylinders).

g. A regulation was established to require that shippers of special form radioactive materials maintain on file a written certification and safety analysis of their special form determination.

h. Requirements were made to clarify the method for "averaging" of multiple wipe samples in the assessment of "significant removable surface contamination," as well as to allow a modified level of removable surface contamination in "full-load" surface vehicles.

i. Regulations were established to add to the motor vehicle and rail carrier regulations provisions for segregation and stowage controls for multiples of packages totalling 50 Transport Indexes or less.

j. Guidance for shippers in completing the written entries on "Radioactive" package labels was inserted into the regulations.

k. Provisions were established for shipments of Fissile Class II packages as a Fissile Class III shipment, as well as co-mingling of Fissile Class II and III packages as a Fissile Class III shipment.

2. Legislation and Regulation Regarding Restriction of Radioactive Materials Transported by Passenger Carrying Aircraft based on End Use.

On January 3, 1975, President Ford signed into law the Transportation Safety Act of 1974 as Public Law 93-633 (The Act) (4). This Act provided the most significant legislation relating to the safe transport of hazardous materials in many years. The declared policy of the Congress in passing this Act was to improve the regulatory and enforcement authority of the Secretary of Transportation to protect the Nation adequately against the risks to life and property which are inherent in the transport of hazardous materials. I shall try to discuss those provisions of the Act which directly relate to transport of radioactive materials.

As a result of Section 108 of the Act, the Secretary of Transportation was required to issue, within 120 days (i.e., by May 3, 1975), regulations which"shall prohibit any transportation of radioactive materials on any passenger-carrying) aircraft unless the radioactive materials are intended for use in, or incident to, research or medical diagnosis or treatment, so long as such materials as prepared for and during transportation do not pose an unreasonable hazard to health and safety." Accordingly, and in response to this mandate, on February 4, 1975, Federal Aviation Adminstration (FAA) of the Department issued a proposal to amend the Federal Aviation Regulations (5). After public hearings and consideration of comments,a final amendment was subsequently issued on April 17, 1975 (6). Effectively this "Section 108" amendment, as I shall refer to it, has significantly changed the previous air transportation situation to the extent that the end use of a radioactive material to be transported must now be taken into account. Unless the material is intended for use in a research or medical application, it may not be offered for transportation on a passenger-carrying aircraft. In practice, the shipper's certification of a shipment offered to an air carrier must contain an appropriate statement on the intended usage of the material. The major net impact of this new requirement, in my view, has been the prohibition of shipment via passenger-carrying aricraft of most industrial shipments, particularly sealed sources used in industrial gamma radiography. Two aspects of this new rule have been controversial. One of these was whether the intent of the new rule was to limit shipments to those for use in "research" generally or to just medical research. The Department has issued a legal opinion to the effect that shipments need not be confined to "medical" research only, but to any type of "research." The other controversial point has been as to whether the term "research" excludes or includes "development." This matter is presently being reconsidered with a view toward clarification.

One aspect of the new legislation (i.e., the adoption of the regulatory definition for "radioactive material") has created the net effect of excluding from passenger-carrying aircraft even those small quantity radioactive packages (for nonmedical or nonresearch uses) which qualify for exemption from the specification packaging, marking, and labeling requirements. In the final amendment, implementing the statute, therefore, an exemption to authorize the continuation of the carriage of such materials was provided under the exemption procedure of the Act itself. Using this process, it will be necessary to republish the exemption every 2 years. The Department hopes to obtain corrective oversight legislation to resolve this matter.

3. Consolidation of the Hazardous Materials Regulations.

On April 15, 1976, the Materials Transportation Bureau of the Department published what may be most extensive and significant amendments to the Hazardous Materials Regulations in probably the last half century. These amendments, referred to as Docket HM-112 involve a consolidation of the regulations for the air, water, rail, and highway modes into a single volume, Title 49 of the Code of Federal Regulations (7). Prior to this time, and throughout history, the regulations have been codified in three separate volumes of the Codes. We expect that this reconsolidation will be a tremendous aid and simplification to both shippers and carriers facilitating their understanding, use of, and compliance with the hazardous materials regulations.

Included in the HM-112 amendments are many other matters of significance; such as the creation of four new classifications for hazardous materials to reduce special problems related to air and water transport; new uniform multimodal vehicle placarding requirements; a standardization of the format for shipping paper descriptions; and the listing of many materials by specific name, rather than generic classification. Although the changes in HM-112 relating to radioactive materials are few in number, it is important to point those few out. They include:

a. A revision to the radiation dose rate criteria for the use of the Radioactive Yellow II package label. Whereas the previous limits were 0.5 mrem/hr at 3 feet (transport index) and surface dose rate of 10 mrem/hr, those limits have been raised to 1.0 mrem/hr at 3 feet, and 50 mrem/hr at the package surface.

b. An expansion of the elements of information required for inclusion on the shipping paper description for radioactive materials shipments.

c. A revision of the proper shipping name listings for the generic, i.e., "N.O.S. or 'not otherwise specified'" listings for radioactive materials.

d. New separate listings by name for enriched and nonenriched uranium hexafluoride, acknowledging its dual hazard properties of being both a radioactive and corrosive material.

e. A revision of the vehicle placards for radioactive materials, adopting the railroad-oriented diamond shape for all modes, utilizing for the first time, the standard radiation symbol on the placard.

In General, the Docket HM-112 amendments become effective on July 1, 1976, except for certain requirements, such as the new placards and others, which will become effective a year later on July 1, 1977.

4. Relationship of Federal Transportation Regulations to Other Laws.

As a result of Section 112 of the Public Law 93-633, the Secretary of Transportation has now been provided with the statutory authority to expressly preempt any requirement of a State or political subdivision, which is "inconsistent with" any requirement of the Act or any regulations issued under the Act (8). However, the Act does provide a mechanism by which a State or political subdivision may obtain authority from the Secretary to maintain requirements which are inconsistent. The purpose of the preemption provisions of the Act is obviously to preclude a multiplicity of State and local regulations and the potential for varying as well as conflicting regulations for the transportation of hazardous materials which might unreasonably burden commerce.

The regulatory procedures to implement the preemption provision of the Act are expected to be issued shortly by the Department. As an initial step in that direction, a notice was issued on March 3, 1976, proposing to amend the DOT regulations so as to revise the statutory authority citations for the hazardous materials regulations from the old citations to those of the new Act (9). This action was necessary in order to utilize not only the preemption provisions of Section 112, but several other provisions of the Act as well. A final amendment on this matter is expected in the near future.

As many of you are probably aware, a number of States and other jurisdictions have in the past year either proposed or adopted restrictive regulations pertaining to transport of nuclear materials. Obviously, the preemption authority and provisions which will become available shortly, are quite relevant to those situations. A strong possibility exists that certain of these restrictions may eventually be determined to be inconsistent with Federal regulations and thereby preempted.

5. Transport of Plutonium by Air.

As a result of congressional legislation in 1975, shippers of plutonium (i.e., NRC licenses or ERDA prime contractors) may no longer ship plutonium by the air mode (10). Specifically, the provisions of Public Law 94-79, signed into law by the President on August 9, and otherwise referred to as the "Scheuer Amendment" reads:

> The Nuclear Regulatory Commission shall not license any shipments by air transport of plutonium in any form, whether exports, imports or domestic shipments; Provided, however, that any plutonium in any form contained in a medical device designed for individual human application is not subject to this restriction. This restriction shall be in force until the Nuclear Regulatroy Commission has certified to the Joint Committee on Atomic Energy of the Congress that a safe container has been developed and tested which will not rupture under crash and blast-testing equivalent to the crash and explosion of a high-flying aircraft.

As yet, neither NRC nor ERDA have certified any plutonium packages to the JCAE under the terms of the new laws. Both NRC and ERDA have therefore issued directives banning the air shipment of plutonium by its licensees and contractors. Each agency, particularly NRC, has been actively engaged in recent months, however, in establishing a certification program, consisting of: (1) evaluation of the conditions which could be produced in severe aircraft accidents; (2) development of qualification criteria prescribing appropriate performance requirements and acceptance standards for shipping containers used to transport plutonium by air; and (3) a series of physical tests and engineering studies of plutonium shipping containers to demonstrate their ability to meet the qualification criteria. Based on the results of this program, it is anticipated that NRC and ERDA will begin a program for certification to the JCAE of plutonium packages for air shipment, sometime in 1976, in fulfillment of the requirements of the "Scheuer Amendment."

6. Monitoring of Radioactive Packages by Air Carriers.

A notice was issued by the Department on December 11, 1975, under Docket HM-131, proposing to require aircraft operators to perform certain inspections and monitoring of radioactive materials shipments (11). This proposal essentially replaced an earlier provision which had been finalized by the FAA on February 4, 1975, and was to have become effective on January 1, 1976. Both the earlier provision, which was revoked on December 11, 1975, and the recent proposal involve the imposition of specific requirements for air carriers to perform radiation surveys on packages of radioactive materials tendered to them by shippers (12). The public comment period on the recent notice expired on February 17, 1976, with this Docket and comments therein presently under staff consideration.

7. Other Miscellaneous Matters Relating to Air Transportation.

At the present time the Department is preparing a notice which would, when published, propose to adopt certain changes as based on recommendations made by the former AEC (now NRC) to the FAA in 1974. Those recommendations are contained in a report entitled "Recommendations for Revising Regulations Governing the Transportation of Radioactive Material in Passenger Aircraft." Copies of this report are on file with both the Department and the NRC. Among the possible proposed changes which would be based on those recommendations are:

(a) establishment of separate limits for amounts of radioactive material allowed to be carried on cargo-only aircraft;

(b) a reduction in the maximum allowable transport index from 10.0 to 3.0 for a package on passenger-carrying aircraft;

(c) a revision in the separation distance tables for stowage of packages on aircraft;

(d) other revisions in the stowage rules for radioactive packages, and;

(e) provisions for combinations of radioactive packages in shipping unit overpacks.

8. Interagency Responsibility - Radiological Incident Emergency Response Planning.

Although it does not involve rulemaking, I would like to mention the December 24, 1975 notice, issued by the General Services Administration, Federal Preparedness Agency (13). The purpose of that notice was to provide full public information concerning the general course and method by which certain radiological incident emergency response planning activities are carried out by the concerned Federal Agencies. This Notice replaced an earlier Notice of January 24, 1973, which dealt with interagency planning for radiological emergencies at Fixed Facilities. The new Notice extends such planning activities to include transportation, as well as fixed facilities and states that the Department of Transportation is responsible for (1) providing guidelines in cooperation with NRC and other Federal Agencies; and consistent with NRC guidance, for the development of that portion of State and local emergency plans pertaining to transportation involving radioactive materials as described in the purpose portion of this statement and (2) assistance to State and local government in emergency planning for such transportation incidents.

9. Amendments to be Proposed Based on International Changes.

Finally, I shall summarize briefly some of the major changes included in the 1973 revised IAEA transport regulations. These can be considered as indicative of the major thrust of the changes which can be expected to be proposed in a forthcoming new Notice being proposed by DOT and also in an anticipated notice of proposed rulemaking being proposed by the U.S. Nuclear Regulatory Commission to its 10 CFR Part 171.

a. A_1/A_2 System - A new method of classifying and limiting radionuclides for purposes of transport, known as the A_1/A_2 system has been established, replacing the "transport group" system. In place of the seven transport groups currently used, the A_1/A_2 system will provide a list of A_1 (maximum quantity of special form material in a Type A package) and A_2 (maximum quantity of non-special form material in a Type A package) values for some 260 specific radionuclides. Procedures are also prescribed for determining A_1 and A_2 values for unlisted radionuclides and mixtures. Except for certain arbitrary upper limits, the A_1 value is based on external radiation level if the contents were to escape from the package and A_2 is based on the hazard of inhalation or ingestion (except where external radiation is more restrictive and then $A_2 = A_1$). While the replacement of the "transport group system" by the "A_1/A_2" system results in lower package limits for some nuclides, for the majority it results in a relaxation of the previously restrictive package limits which were set on the basis of the most radiotoxic nuclide in a particular transport group.

Effective use of the A_1/A_2 values is also used to set the package content or activity limits for small or exempt quantities, radioactive devices, low specific activity materials, packages for postal shipments, and for a new category: low-level solid radioactive material.

b. Activity Limits for Containment of Type B Packages - In recognition of the fact that "zero loss" for a Type B package is technically unattainable, the 1973 standards provide quantitative allowable releases after the normal and accident damage tests. These limits are expressed in very small fractions of the A_2 values for Type B(U), Type B(M) packages not designed for continuous venting, and Type B(M) packages specifically designed for continuous venting. It is expected that these quantitative standards will enable the various competent authorities to apply the package integrity standards in a more uniform fashion.

c. Establishment of an LLS (Low Level Solid Radioactive Material) Category - Comments by several member States to the IAEA indicated a need for the revised regulations to provide for a category of material, which in itself could not meet the precise technical prescription of LSA materials, wherein dependence for safety is not placed upon any specified packaging requirements. Subject therefore to the prescription of certain minimal packaging requirements of the UN Committee on Dangerous Goods, "LLS" category, directed at low and medium activity solid wastes was established. The parameters for qualification of a material as "LLS" are as follows:

(i) The activity under normal transport conditions is and remains distributed throughout a solid or a collection of solid objects or is and remains uniformly distributed in a compact binding agent and does not exceed an average of 2×10^{3} A_2/gram and that even under loss of outer packaging the activity loss per package per week resulting in total immersion in water does not exceed 0.1 A_2 Ci; or

(ii) For objects of nonradioactive material contaminated with radioactive material, the contamination is in a nonreadily dispersible form (i.e., all loose contamination removed by thorough cleaning) and the contamination level averaged over 1 m^2 of the surface does not exceed 2 $\mu Ci/cm^2$ for high toxicity alpha emitters and 20 $\mu Ci/m^2$ for all other radionuclides.

The new IAEA regulations also clarify and greatly limit the range of materials which might qualify as "low specific activity," using the A_1/A_2 conceptual basis. This limitation led to the establishment of this new category "LLS" or "low level solid radioactive material."

d. Point of Measurement of the Transport Index - Another important change to the 1973 IAEA regulations is the point of measurement of the transport index. Whereas in the 1967 regulations the transport index is defined as the dose rate in millirem per hour at 1 meter from the center of the package, in the 1973 regulations it has been changed to 1 meter from the external surface of the package. For the U.S. Regulations, very little change in its definition will therefore be required since at the present time the transport index is defined as the dose rate at 3 feet from the external surface of the package. This change in the point of measurement by the IAEA is a reversion to the definition used in the original 1961 IAEA Regulations. It is expected that the practical determination of the transport index will be greatly simplified by the change.

e. Change in Criteria for Use of Radioactive YELLOW II Label -Another change involves an upward revision in the allowable radiation at the surface and at 1 meter from packages allowed to bear the Radioactive-Yellow II category label. The change allows for an increase from 0.5 mrem/hr at 1 meter (transport index) to a limit of 1.0 mrem/hr and also at any point on the accessible surface of the package to 50 mrem/hr.

f. Change in Format - A frequent criticism of the 1967 IAEA Regulations has been its format, which has been very confusing and time-consuming for the occasional user. As a result of the numerous comments, the IAEA Secretariat has rearranged the format of the 1973 edition into a much more readily usable form and one which facilitates the incorporation of IAEA Regulations into other regulatory documents. In addition, a set of 12 schedules or annexes listing in abbreviated form the requirements to be met for the transport of specified types of consignments have been appended to the regulations. These schedules are intended to aid the user and do not contain any requirements in addition to those appearing in the main body of regulations.

g. Package Test Procedures - The 1973 revisions to IAEA Regulations are not imparting any major changes to the procedures specified for the assessment of the performance of special form material or for Type A or B packages. The few changes which have been made, however, include:

1. The introduction of a 15-meter immersion test for the criticality assessment of fissile packages wherein reliance is placed on the assumption of no water in leakage due to package integrity;

2. A requirement that each of the Type A performance tests is to be preceded by the water spray test;

3. The introduction of a penetration test for Type A packages containing liquids and gases; and

4. The grading of drop heights for the free drop of very heavy Type A packages.

In a major decision, the Review Panel also decided to retain the requirement for competent authority certification of "special form" radioactive materials. The United States had sought vigorously at each Panel meeting to obtain the deletion of this requirement.

h. Deletion of the "Large Radioactive Source" Terminology - It should be noted that with the adoption of the A_1/A_2 concept, the "Type B age activity limits has been deleted. As pointed out earlier, the design assessment of Type B packages has been established on the multilateral/unilateral principle, with respect to the competent authority approval of the package design. The Revision Panel, however, felt that it would be desirable to retain a requirement for notification to other competent authorities for international shipments, prior to these shipments which exceed certain levels; i.e., $3 \times 10^3 A_1$, or $3 \times 10^3 A_2$, as appropriate, or 3×10^4 curies, whichever is the least.

This "notification" level in a sense parallels the previous large radioactive source threshold.

i. Establishment of an "Advisory Document" - Immediately following the second Revision Panel in October 1971, the IAEA convened a followup 1-week "Revision" Panel, with the chartered objective of developing a companion "advisory" document to the basic regulations. This Panel prepared a draft of such an advisory document consisting of:

1. Material of an advisory nature which had been included in the 1967 regulations and removed by the Regulatory Panel;

2. Material in documents considered by the Regulation Revision Panel and referred to the Advisory Panel and accepted by it; and;

3. Other material provided by the members of the Advisory Document Panel.

The companion advisory document comprises a very helpful "how to" type document, supplementing the "what to" context of the regulations, per se. Whereas the next regulatory revision of Safety Series No. 6 is not contemplated for 10 years, the IAEA is planning on a review and update of the advisory document at, roughly 2-1/2-year intervals. The first issuance of the advisory document, as IAEA Safety Series No. 37, took place in late 1973 (Document STI/PUB/324).

Many of the IAEA regulatory changes discussed above reflect proposals which had been originated and proposed by the Panel participants from the United States. The major and significant impact of the overall changes is expected to be in two major areas: (1) the elimination of the "transport groups" and conversion to the "A_1/A_2 system" for classifying radionuclides and (2) the reassessment of Type B package designs to qualify the allowable loss and leakage rates after both normal and accident damage tests, as well as to determine whether such packages meet the unilateral or multilateral criteria with respect to international movements.

As of this date, the 1973 revised IAEA standards have already been adopted by most other major countries, as well as the two international transport associations, IATA (International Air Transport Association) and IMCO (Inter-governmental Maritime Consultative Organization). The adoption of the appropriate changes by the United States as rapidly as possible is becoming increasingly vital in order to maintain compatibility between the domestic and international regulations.

REFERENCES

1. Paper, "An Update on the Status of Recent and Proposed Changes to the U.S. Regulations for Transport of Radioactive Material," from the "Proceedings of the Fourth International Symposium on Packaging and Transportation of Radioactive Materials," Sept., 22-27, 1974, Miami, Florida. Published as CONF-740901-P1, available from NTIS, Springfield, Virginia.

2. Docket HM-111, "Miscellaneous Proposals Relating to Radioactive Materials," FEDERAL REGISTER, Vol 38, No. 205, p. 29483, October 25, 1973.

3. Docket HM-111, "Radioactive Materials, Miscellaneous Amendments," FEDERAL REGISTER, Vol. 39, No. 252, p. 45238, December 31, 1974.

4. Public Law 93-633. 93d Congress, HR 15223, January 3, 1975, 88 Stat 2156, 49 USC 1808.

5. FEDERAL REGISTER, February 4, 1975, 40 FR 5168, Notice 75-2 Docket 14249, 14 CFR Part 103.

6. FEDERAL REGISTER, April 17, 1975, 40 FR 17141, Amendment No. 103-24, Docket 14249, 14 CFR Part 103.

7. FEDERAL REGISTER, April 15, 1976, Part III "Consolidation of Title 14, Part 103 and Title 46, Part 146 in Title 49, 41 FR 15792.

8. Public Law 93-633, 49 USC 1811.

9. FEDERAL REGISTER, March 3, 1976, Docket HM-134, Notice No. 76-2, 41 FR 9188, 14 CFR Part 103, 46 CFR Parts 64 to 146, 49 CFR Parts 171-179.

10. Public Law 94-79, August 9, 1975 and Public Law 94-187, December 31, 1975.

11. FEDERAL REGISTER, Docket HM-131, Notice No. 75-10, 40 FR 57688, December 11, 1975, "Proposed Inspection and Monitoring Requirements for Radioactive Materials."

12. FEDERAL REGISTER, Docket No. 13668, Amendment No. 103-26, 40 FR 57667, December 11, 1975, "Carriage of Radioactive Material," 14 CFR Part 103.

13. FEDERAL REGISTER, December 24, 1975, 40 FR 59494, General Services Administration, Federal Preparedness Administration "Radiological Incident Emergency Response Planning; Fixed Facility and Transportation, Interagency Responsibilities."

APPENDIX I

Resolution Published in "The City Record" on Tuesday January 20, 1976

HEALTH SERVICES ADMINISTRATION
DEPARTMENT OF HEALTH

Resolutions Adopted

AT A MEETING OF THE BOARD OF HEALTH OF THE DEPARTMENT OF Health held January 15, 1976, the following resolution was adopted:

Resolved, that section 175.111 of the New York City Health Code, as repealed and reenacted by resolution adopted on the fifteenth day of November, nineteen hundred seventy-three and filed with the City Clerk on the twentieth day of November, nineteen hundred seventy-three, be and the same hereby is amended by adding a new subsection (1) thereto, to follow subsection (k) thereof, to be printed together with explanatory notes, to read as follows:

(1) Notwithstanding the foregoing provisions of this section, a Certificate of Emergency Transport issued by the Commissioner or his designated representative shall be required for each shipment, to be transported through the City or brought into the City, of any of the following materials:

(1) Plutonium isotopes in any quantity and form exceeding two grams or 20 curies, whichever is less;

(2) Uranium ennriched in the isotope U-235 exceeding 25 atomic per cent of the total uranium content in quantities where the U-235 content exceeds one kilogram;

(3) Any of the actinides (i.e., elements with atomic number 89 or greater) the activity of which exceeds 20 curies;

(4) Spent reactor fuel elements or mixed fission products associated with such spent fuel elements the activity of which exceeds 20 curies; or

(5) Any quantity of radioactive material specified as a "Large Quantity" by the Nuclear Regulatory Commission in 10 CFR Part 71, entitled "Packaging of Radioactive Material for Transport."

NOTES: Subsection (1) was added by resolution adopted on January 15, 1976 to require the approval of the Commissioner or his designated representative through the issuance of a Certificate of Emergency Transport for the transport or the bringing into this City of specified large quantities of plutonium, enriched uranium and other actinides and spent reactor fuel elements which would present a great hazard to public health in this densely and highly populated City. It is intended that such Certificate will be issued for the most compelling reasons involving urgent public policy or national security interests transcending public health and safety concerns and that economic consideration alone will not be acceptable as justification for the issuance of such Certificate. Such Certificates are also intended to be issued for hectocurie and kilocurie cobalt-60 and cesium-137 teletherapy sources employed in therapeutic radiology and biomedical research or educational purposes and for medical devices designed for individual human application (e.g., cardiac pacemakers) containing plutonium-238, promethium-147 or other radioactive material. This subsection is not intended to apply to small quantities of specified radioactive materials intended for therapeutic radiology and biomedical research or educational purposes

Resolved, further, that subsection (c) of section 175.111 of the New York City Health Code, as repealed and reenacted by resolution adopted on the fifteenth day of November, nineteen hundred seventy-three and filed with the City Clerk on the twentieth day of November, nineteen hundred seventy-three, be and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

(c) This section shall not apply to radiation sources shipped by or for the United Staets Government for military or national security purposes or which are related to national defense. Nothing herein shall be construed as requiring the disclosure of any defense information or restricted data as defined in the Atomic Energy Act of 1954 and the Energy Reorganization Act of 1974, as amended.

NOTES: Subsection (c) was amended by resolution adopted on January 15, 1976 to conform its provisions with subsection (1) adopted by the same resolution.

Resolved, further, that this resolution shall take effect immediately.

A true copy.

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PATRICIA J. CARUSO, Acting Secretary.

APPENDIX II

The City of New York

DEPARTMENT OF HEALTH
BUREAU FOR RADIATION CONTROL
325 Broadway
New York, N. Y. 10007

CERTIFICATE NUMBER

CERTIFICATE OF EMERGENCY TRANSPORT
For
SHIPMENT OF RADIOACTIVE MATERIAL THROUGH THE CITY OF NEW YORK

Bearer is herewith authorized in accordance with Section 175.111 of the New York City Health Code (as amended on January 15, 1976).

NAME OF SHIPPER	ADDRESS OF SHIPPER
NAME OF CARRIER	ADDRESS OF CARRIER
NAME OF CONSIGNEE	ADDRESS OF CONSIGNEE
POINT OF NEW YORK CITY ENTRY	DESTINATION IN NEW YORK CITY
POINT OF NEW YORK CITY EXIT	DATE AND ESTIMATED TIME OF NEW YORK CITY ENTRY
MATERIAL TO BE SHIPPED - DESCRIPTION - ACTIVITY IN CURIES	
DATE OF AUTHORIZATION	NAME OF AUTHORIZING OFFICIAL *(Commissioner of Health or Designated Representative)*

RAD 25 (1/76)

PUBLIC HEALTH ASPECTS OF TRANSPORTATION OF RADIOACTIVE MATERIALS IN LARGE URBAN AREAS

Dr. Leonard R. Solon
Director
Bureau for Radiation Control
New York City Department of Health

On January 15, 1976, the City of New York Board of Health at its regularly scheduled meeting unanimously passed an amendment of the New York City Health Code. The thrust of this amendment is to severly restrict shipments into and through the City of certain categories and quantities of radioactive materials including plutonium, uranium highly enriched in the fissionable isotope uranium-235, and irradiated nuclear fuel elements.

On the same day, the United States Attorney for the Southern district filed suit in Federal court requesting a preliminary injunction to prevent New York City from enforcing its new regulations. One of the putative motivations for the requested judicial relief was the status of truck shipments of spent fuel elements from Brookhaven National Laboratory s High Flux Beam Reactor (HFBR) which previously had been using New York City streets en route to their destination at a United States Energy Research and Development Administration nuclear fuel reprocessing center at Savannah River, South Carolina.

On January 23, 1976, New York City prevailed in the initial legal encounter with Federal authorities when the request for a preliminary injunction was denied by Federal Judge Inzer B. Wyatt. The juridical confrontation continues.

The Brookhaven HFBR shipments were resumed, completely bypassing New York City by transporting the spent fuel over ferry crossing Long Island Sound between Orient Point, Suffolk County, Long Island and New London, Connecticut. Orient Point is east of Brookhaven National Laboratory and the all-land route, through New York City to the west, is no longer employed.

The diversion of these shipments away from New York City has resulted in scrutiny and contemplation of possible regulatory action by officials of Suffolk County and the State of Connecticut. I propose to discuss the public health genesis of the New York City regulation. The text of the radioactive transportation amendment and a sample copy of the Certificate of Emergency Transport for Shipment of Radioactive Material through the City of New York are appended to this report as Appendix I and Appendix II, respectively.

Staff Position of Bureau for Radiation Control, City of New York Department of Health.

On November 6, 1975, the Board of Health of the City of New York held public hearings considering the transportation regulation which it was subsequently to adopt on January 15, 1976.

The original resolution offered for consideration by the New York City Board of Health was modified to take into account recommendations made at the public hearings and in other written submissions made to the Board. These recommendations resulted in textual clarifications pertaining particularly to biomedical applications.

Opponents of the amendment, erroneously in the judgment of the New York City Health Department staff, have inadequately evaluated and grossly underestimated the serious public health implications and potentially disastrous consequences in the employment of major urban population centers, particularly the streets, highways, and airports of New York City, as conduits for exceptionally hazardous radioactive shipments - especially spent reactor fuel elements, isotopes of plutonium, and uranium highly enriched in the fissionable nuclide uranium-235.

What is the background and thrust of the resolution?

For many years the streets of New York City have routinely been used for the transportation of a relatively limited number of shipments of large quantities of radioactive materials. Representative of these transports were shipments over New York City streets and bridges to John F. Kennedy Airport or shipment by air into and out of the United States of large quantities of fixed isotopes of plutonium. Now the quantity of a radioactive material can be expressed either in terms of its mass or weight in kilograms or pounds - or, what is generally of greater significance in evaluating the biological hazard, the activity in curies which is a measure of the rate at which the radioactive substance decays or emits ionizing radiation such as alpha particles, beta radiation, gamma radiation or, for certain actinides or transuranics, or transplutonics, experiences spontaneous fission.

Public Health Concerns of Plutonium Air Shipments

Single shipments of reactor-produced plutonium which have been made within the last year have contained of the order of 100 pounds of mixed isotopes of plutonium-238, -239, -240, -241, -242 with aggregate activities of the order of 500,000 curies. This is an absolutely astonishing number. One will recall the enormous and justifiable furor by the world scientific community which led to the discontinuance of atmospheric weapons testing by the only strategic nuclear powers at the time. The total plutonium activity released to the atmosphere by all the powers to this hour (i.e., the United States, the Soviet Union, the United Kingdom, China, France, and India) is about 400,000 curies, about the same or somewhat less than the contents of a single shipment in or out of Kennedy Airport which occurred six times in the year preceding the enactment of our regulation.

Dispersion of even a small fraction of the contents of one of these shipments as the result of an air crash, concomitant fire, and high winds within the City of New York - air crashes which regrettably occur with the small but lamentable inevitability dictated by Poisson statistics - could have cataclysmic results bringing death or serious injury to thousands of New Yorkers. The inhalation or ingestion of milligram quantities of plutonium would result in almost certain death of an individual within weeks or months. Inhalation of a quantity one hundred fold smaller - tens of micrograms - would result in that person having a special susceptibility to fatal pulmonary cancer in one or two decades. To recapitulate, one milligram, death - 10 micrograms, lung cancer - one air shipment 40,000,000 milligrams or 40,000,000,000 micrograms.

This is not arcane knowledge which exists only in the files of the Bureau for Radiation Control of the New York City Department of Health. These facts are well known to members of the Nuclear Regulatory Commission, the Energy Research and Development Administration, and the great power companies, power reactor manufacturers and national laboratories comprising our nuclear establishment. Why then did it take a vigorous and alert United States Congress to even partially interdict air shipments of plutonium by licensees of the Nuclear Regulatory Commission? This finally took place in the summer of 1975 over the strenuous objections of the Nuclear Regulatory Commission and after a valiant but regrettably unsuccessful juridical fight by the New York State Attorney General. Are we confronting a malevolent conspiracy by calculating men cruelly unconcerned with the public well being? Of course not.

The answer is much simpler and in some ways more terrifying. There is a certain massive intellectual inertia possessed by large influential scientific organizations staffed by the most competent and well meaning of scientists and engineers who, with ingenuity and scholarship, can rationalize and justify almost anything. This includes the preposterous technical obscenity of plutonium air shipments into New York City. The latest justification for this is NUREG-0034 the Draft Environmental Statement on the Transportation of Radioactive Materials by Air and Other Modes issued in March 1976 by the Nuclear Regulatory Commission.

Those of us entrusted with the health and safety of the public have the special responsibility of subjecting these scientific absurdities to the most searching scrutiny in careful defense of the public interest, irrespective of the prestigiousness, influence, high position and skill of their perpetrators.

As an illustration: Last year the New York City Commissioner of Health raised the question of the adequacy of the 30-foot drop test on hard impact surface required by the Code of Federal Regulations, Title 10, Part 71, Appendix B for containers of certain high-risk categories of radioactive materials used in air and surface transportation shipments. In particular the Commissioner questioned the relevance of such a test to the survivability of a plutonium container to a crash in New York City.

Several months later, senior scientific representatives of three Energy and Research Development Administration Laboratories (i.e. Brookhaven National Laboratory, Battelle-Northwest, and Sandia Laboratories) met with a Deputy Commissioner and an Assistant Commissioner of the New York City Health Department. They furnished a document dated September 1975 entitled Air Drop Test of Shielded Radioactive Material Containers (SAND 75-0276) authored by Ivan G. Waddoups of Sandia Laboratories, Albuquerque, New Mexico.

To quote a short relevant portion:

> "Two lead-shielded containers were dropped from 2000 feet onto hard prairie as a visible and easily understood demonstration of the ability of such containers to retain integrity under extremely adverse environment. The OD-1 cask, which weighs 16,300 lbs. (7410 kg), was used to ship and store spent fuel elements from an Oak Ridge research reactor. The B of E 83 container, which weighs 6,720 lbs. (3054 kg), was used in handling irradiated test capsules. Both are considered obsolete since they were not designed to survive the current fire requirements.
>
> "The B of E 83 incurred no measurable deformation, but the OD-1 experienced superficial deformation which would not have resulted in release of the contents."

Get the picture. A 2000-foot air drop from a helicopter is performed and could lead one to the conclusion that even these obsolete containers - there are now better ones - will remain intact after hitting the ground at 246 miles per hour - on not ordinary prairie but "hard" prairie.

However, the author of this really very good and interesting Sandia Report is too forthright a scientist or engineer to leave the reader with what would be clearly an erroneous and misleading conclusion. The last paragraph of the report states:

"Comparing these results with the observed results of the 2000-foot drop test leads the author to the conclusion that the 30-foot drop test onto an unyielding surface is a more severe environment than the 2000-foot drop onto a hard soil."

Did the welcome visitors to the New York City Health Department read and understand their own report - or did they think we would not? How about a 2000-foot air drop not onto so-called hard prairie but an unyielding surface like a runway at Kennedy Airport in Queens or Broadway in Manhattan?

Public Health Concerns of Spent Reactor Fuel Truck Shipments

I would now like to treat another aspect of the New York City regulation -the question of the transportation of spent reactor fuel elements by truck.

For about a decade, Brookhaven National Laboratory has dispatched through the City of New York a limited number of highly radioactive shipments of irradiated fuel elements comprised principally of 93 percent enriched uranium-235. Since the first of January 1975 and through the end of October 1975, there have been 12 shipments from the High Flux Beam Reactor at Brookhaven. Each shipment, involving of the order of 300,000 curies of mixed fission products were carried by truck in a specially engineered shielded cask. While in the City of New York, it is escorted by a New York City Police Deparment vehicle until outside City jurisdiction. Subsequently, our surveillance of such shipments has intensified and radiation specialists of the Bureau for Radiation Control have augmented the regular police escort. These are intrinsically hazardous shipments completely unrelated to national security or defense and were terminated under the provisions of the amendment to the Health Code.

However, as dangerous as these Brookhaven shipments are, they are only the tiny tip of an almost unbelievable radioactive iceberg which is contemplated for New York City by an electric power company neighbor to the East - the Long Island Lighting Company - LILCO. What is the scenario which Long Island Lighting Company is orchestrating - without having consulted the City of New York Health Department - nor, to our knowledge, any other responsible agency of this City?

At Shoreham, Suffolk County, on the north shore of Long Island - 56 miles east of the borough of Queens, Linc, the Long Island Lighting Company has completed about 50 percent of a boiling water nuclear power station with a generating capacity of 819 electric megawatlts (MWe). This reactor will employ fuel only slightly enriched (between 3 percent and 5 percent) in the fissionable isotope uranium-235. It should be mentioned, parenthetically, that fresh unirradiated reactor fuel of this low enrichment does not constitute either a radiological or nuclear criticality hazard and will not be influenced by the New York City Health Department transportation regulation.

However, when the Shoreham reactor becomes operational in 1978 and begins shipping its irradiated fuel to reprocessing centers, the City was supposed to become host to between an additional 35 and 70 truck shipments each year through New York City streets - each shipment carrying several million curies of mixed fission products and tens of thousands of curies of plutonium and other actinides.

In addition, Long Island Lighting Company has in an advanced state of planning two pressurized water reactors each of 1150 electrical megawatt capacity at Jamesport, Suffolk County, about 18 miles east of Shoreham. These are scheduled to begin operation in 1983 and 1985, respectively. These reactors will have added an additional 150-160 shipments annually of spent fuel through

City streets - again each shipment carrying of the order 2.5 million curies of mixed fission products and between 30,000 and 40,000 curies of plutonium and other actinides. Thus adding up the totality of shipments from Brookhaven, Shoreham, and Jamesport there was to have been between 200 and 250 shipments of these cargos of potential malignancy inducing materials traversing New York City each year.

Human Error, Accident, Diversion, and Sabotage

Now the casks which carry these shipments are carefully engineered in terms of radiation shielding, heat dissipation, and mechanical integrity. However, they are only well-engineered, not perfectly engineered - and subject to human error, accident, diversion and sabotage. I do not know, and I suspect no one else really knows either, the priori probability of a cataclysmic truck accident or the deliberate destruction or diversion of a radioactive shipment by a terrorist or criminal organization.

However, for the sake of calculation, if the probability of such an occurrence in an individual shipment is one in a thousand, there will be a 50 percent chance of at least one disaster with 200 shipments a year between 3 and 4 years. The odds may be better or worse. Suppose the chance of avoiding disaster in a single shipment is better: i.e., ten-thousand to one against; then there is a 50 percent chance that a cataclysm will not occur for 34.6 years. However, it is in the nature of stochastically governed events such as this, that one cannot know whether a disaster will occur in the very first shipment or will be deferred indefinitely. The conclusion is fundamentally the same. Shipments such as these are unacceptable into the City of New York.

I would like to affirm that the New York City regulation, irrespective of what inferences some of our well-intentioned supporters or our respected adversaries wish to draw, is not anti-nuclear. In fact, we recognize the compelling need for and support nuclear power technology until a more suitable energy option becomes available. However, we insist that this technology evolve with careful and objective respect and full disclosure of the very serious public health and environmental questions involved.

Alternatives to Transportation Through New York City

There are alternatives available to both Brookhaven National Laboratory and the Long Island Lighting Company instead of the unacceptable, unwanted, and unscientific truck shipments of irradiated fuel through New York City. (1) For the immediate short-term, one can bypass New York City by the use of barge shipments on waterways bypassing New York City. (2) For the longer-term future developments of nuclear technology in this area and throughout the United States, we endorse the nuclear center concept - secure integrated facilities where the entire nuclear cycle from fuel element fabrication through nuclear power generation and fuel element reprocessing can be achieved in one place - essentially eliminating the very dangerous and highly vulnerable transportation link.

Science, Public Health, and the Legal Aspect

Finally, I would like to reassert the primacy of the scientific and public health questions over the legal construct in the whole matter under review. If the legal posture of certain opponents of this amendment is correct, and we by no means concede this to be the case, and the Department of Transportation and the Nuclear Regulatory Commission have indeed preempted this vital area of local public health and safety regulation. I submit that the people once again must invoke Federal legislative action to rectify a grotesque situation which goes against good science and good public health.

Conclusions

To synopsize the principal points of this paper:

(1) Good science and good public health dictate the avoidance of heavily populated urban centers for hazardous shipments of radioactive materials.

(2) Accidents and/or criminal or terrorist diversion of large shipments of radioactive materials maximize the population risk in large cities.

(3) Integrated nuclear centers with co-location of important elements of the nuclear fuel cycle such as power generation, fuel element fabrication, spent fuel reprocessing, and waste product management, will reduce the very vulnerable and hazardous transportation link. Necessary physical security and radiological surveillance can be obtained in no other way.

TRANSPORTATION OF RADIOACTIVE MATERIAL IN ILLINOIS

Philip N. Brunner
Illinois Department of Public Health

The subject of my brief talk this morning concerns the status of radioactive material transport in the State of Illinois. Since this particular subject is high on our State priority list, perhaps it would be useful to you if I would briefly outline the events that led up to our current activity in this area.

During the past 2 to 3 years, there has been an increasing public concern with the transportation of all hazardous materials within and through our State. This concern may not be any more or less than you might be facing in your own States. In our State, however, there have been some circumstances which tended to heighten the intensity of public concern. For example, hardly a week goes by that we don't have at least one or two train derailments or train-related accidents. While most of these have not resulted in any serious consequences, the frequency of their occurrences is certainly indicative of problems with that transportation system. In July of 1974, however, a train related incident involving propane occurred in Decatur, Illinois, a town 38 miles due east of Springfield, which resulted in multiple fatalities and extensive property damage. This accident was not unlike one that happened several years ago that nearly wiped out the town of Crescent City, Illinois. While these accidents did not involve radioactive substances, radioactive shipments could have been on those trains.

Because the definition of hazardous substances generally includes radioactivity, the transportation of radioactive materials has fallen under the umbrella of concern for all hazardous substances transport. Since the spring of 1974, there have been 21 transportation related incidents reported to us involving radioactive substances. While the majority of these accidents have not resulted in any release, due in large part to current packaging requirements placed on the shipper, the frequency of this type of accident is also indicative of a potential problem.

Within the past year, the Department has participated in two studies involving the transport of radioactive substances. The first study began in the fall of 1974 through a contractual arrangement with the U.S. Nuclear Regulatory Commission and the U.S. Department of Transportation. Several of you have also participated in contract studies under this federally assisted program, and I for one feel this type of State/Federal program can be highly beneficial to help us understand the true transportation problem. Our particular study was centered around O'Hare Field in Chicago. During our 3 month period of contractual study, we looked at transportation patterns, volume, handling of radioactive packages, radiation exposures to freight handlers, and the status of compliance with existing Title 49 regulations. I think generally the final analysis of the study confirmed the thoughts that we had prior to entering the program that there is considerable amount of transport within the State of Illinois, and in particular, in the O'Hare-Chicago area. This is due in large part to the large nuclear related industries that do business in that area. I would be happy to send, upon request, a copy of this study if you will just drop me a line. In our summary statement of this study, we concluded that:

1. Areas of noncompliance were generally found with transportation systems or shippers who only occasionally ship packages of radioactive materials and are not familiar with the applicable regulations or are confused with the regulations when they try to interpret them. We also found instances where facilities or shippers were simply not aware of any regulations pertaining to the shipment of radioactive materials.

2. We also found during our survey, that 50 percent of the surface vehicles that were required to be placarded were either not placarded, or were placarded improperly. Since our survey was concentrated heavily on operations at O'Hare Field, most of our surveys of surface vehicles were related to secondary transportation revolving around airline operations.

3. In the area of freight handling of radioactive packages, the survey determined a rather good positive attitude in the general handling of these types of packages. We did, however, find that certain handlers were not as informed as they should have been concerning the proper handling and that there was a need for education for certain transportation firms. We found that the present requirements for labeling packages on two sides lead to identification problems for the freight handlers because positioning of the package on conveyor lines could obscure the labels.

All things considered, the survey generally indicated that the problems that were found could be relieved through education and closer regulatory surveillance. We were pleased to find that personnel radiation exposures to freight handlers were less than we had anticipated prior to beginning the survey.

The second study in which we participated was a hazardous material transportation survey, performed in cooperation with the Illinois State Police, Department of Transportation, and Civil Defense Agency. The purpose of this study was to survey truck traffic on the major highways of our State to determine the volume of hazardous materials being transported and the existing level of compliance with existing transportation regulations. The study was conducted at State-owned weight stations on the major interstate highway systems in the north part of the State. Members of the uniformed Illinois State Police were trained to carry out this month-long study. Essentially, the survey consisted of checking the freight manifest on all placarded trucks going through the weight station to determine correctness and applicability of placards. For the radioactive portion of this study, a 2" x 2" sodium iodide detection system and a Model RM-17 radiation monitor, on loan from the Eberline Instrument Company, were used. During the survey period, a total of 27,486 trucks crossed these scales, of these, 756 trucks bearing hazardous materials placards were examined to determine the nature of hazardous material being transported, the origin and destination of the load, and the quantity of material involved. The hazardous shipments only accounted for 2.75 percent of the total survey, below pre-survey estimates of 5 to 10 percent. Several factors probably accounted for this reduced volume, one being the network of CB radios used by the trucking industry. Only 10 trucks were found to have radioactive material on board but our detection system with a pre-set alarm device worked extremely well and we even found one truck carrying monzonite sand. A copy of this report can also be obtained from me if you will simply write and ask for the Hazardous Material Transportation Survey Report.

Based upon information that was available to us through regulatory channels and through the two limited surveys with which we were involved, the Department began to examine the avenues that were open to State involvement in the area of transportation of radioactive materials. We discussed the feasibility of adopting Federal Department of Transportation, Title 49 regulations with members of the U.S. Department of Transportation both in Washington and regionally, with out sister State agencies, and with the U.S. Nuclear Regulatory Commission. We were of the opinion that existing transportation regulations appeared adequate. However, there was a stimulus needed to assure that these regulations were being met within our State. We proposed a new regulation C.100 for radioactive material transportation that was adopted by reference to the U.S. Department of Transportation Regulation. We dropped our existing exemption for carriers from our regulations. After this regulation was drafted, it was shared with the U.S. Department of Transportation, we were advised that the inclusion of intrastate and interstate carriers into these regulations would be proper and we were encouraged to follow these steps.

The proposed regulations were then distributed and a public hearing was held on October 22, 1975. While there was limited attendance at the hearing, strong positive support was given by the Illinois Trucking Association for this proposed regulation. They had published this draft in their various news letters and received no adverse comment. The regulations became effective November 26, 1975. It will be the Department's intent to work with other Illinois State agencies to implement programs of surveillance and enforcement in order to strengthen the care with which radioactive materials are transported. There are many companies that are routinely involved in transporting material of this type and they do so in a very satisfactory manner. The State believes that the areas where we can have the biggest impact are with the nonroutine haulers and shippers who are not fully aware of existing regulations.

In summary, I think you might be interested in a circumstance that happened during the conduct of our O'Hare survey. Prior to the initiation of the study, we, as well as the Argonne Response Team, had received numerous reports on minor accidents involving packages of radioactive material. In fact, there were months when we had multiple occurrences at O'Hare Field alone. As soon as that study began, and even to this day, it is a rare occurrence to receive a call with this kind of problem and I think that probably reinforces the fact that if people know surveillance is going on and become aware of the potential problem these shipments represent, then the accident rate will decrease significantly.

NBS Radiation Measurement Assurance Activities

Elmer H. Eisenhower
Assistant to the Director
Center for Radiation Research
National Bureau of Standards

INTRODUCTION

Since this is the first time NBS has appeared on the program of this annual meeting, an introduction is in order. The National Bureau of Standards is a nonregulatory Federal agency in the U.S. Department of Commerce with legislated responsibility for the custody, maintenance, and development of the national standards of measurement, and the provision of means and methods for making measurement consistent with those standards. In carrying out this function, NBS is authorized to investigate radiation, radioactive substances, and x rays, their uses, and means of protection of persons from their harmful effects. Additionally, NBS is charged with exercising its functions for any State or municipal government within the United States, and is authorized to prepare and distribute standard instruments, apparatus, and materials for calibration of measuring equipment.

In the general area of radiation measurements, NBS activities are divided organizationally and geographically into the specific areas of ionizing and nonionizing radiation. Those activities concerned with ionizing radiation measurements are conducted within the Center for Radiation Research, located in Gaithersburg, Maryland, while the work relating to nonionizing radiation is done in the Electromagnetics Division in Boulder, Colorado.

During the past 6 years, NBS has placed increasing emphasis on studying the national system of measurements, the NBS role in the system, and methods for strengthening the system. Specifically, it has become obvious that more attention must be paid to provision of means and methods for making measurement consistent with the national standards maintained by NBS. If the various measurements made nationally are consistent with the national standards, they will also be consistent with each other and the national measurement system will be functioning properly. To achieve and maintain the necessary degree of consistency, suitable methods must be implemented for assurance of measurement quality. This requires continued operation of a measurement assurance program that monitors performance of the measurement makers and takes the steps necessary to improve performance as needed. It is only through operation of a satisfactory measurement assurance program that the concept of traceability to national standards can become meaningful.

PRESENT MEASUREMENT ASSURANCE PROGRAMS

It is helpful to visualize measurement traceability as a pyramidal structure (Fig. 1) with the Bureau International des Poids et Mesures (or the International Atomic Energy Agency in the case of developing countries) at the apex as the organization that provides for measurement consistency at the international level. At the second level are the national standards laboratories such as NBS who are responsible for measurement consistency in their own countries.

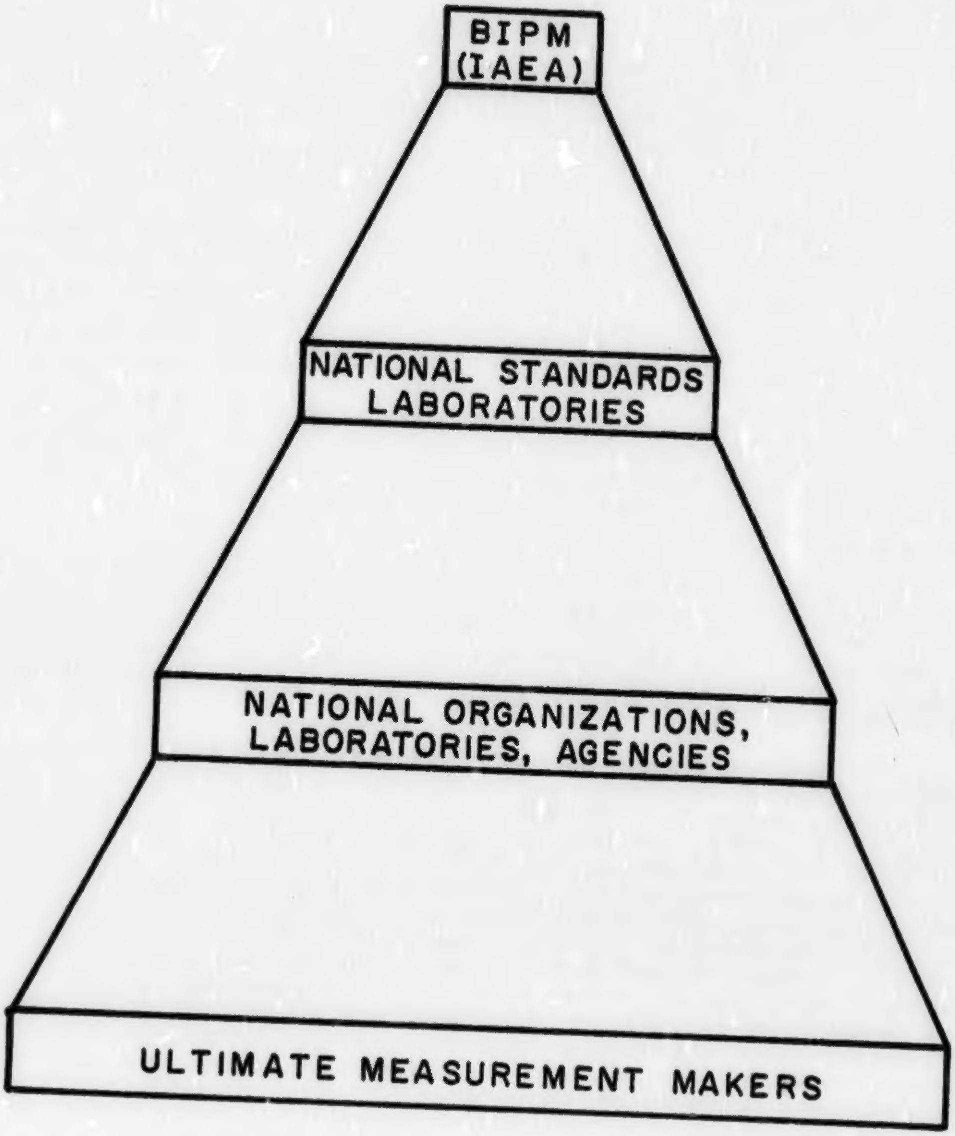
BIPM
(IAEA)
NATIONAL STANDARDS LABORATORIES
NATIONAL ORGANIZATIONS, LABORATORIES, AGENCIES
ULTIMATE MEASUREMENT MAKERS

Figure 1. Structure for measurement traceability.

Because of its limited resources, it is impossible for NBS to maintain direct traceability to the many thousands of measurement makers in the United States. Thus it is generally preferable to maintain measurement consistency through national organizations, laboratories, or agencies that are themselves traceable to NBS through a measurement assurance program. The following examples of ongoing programs will illustrate the function of the third level of the pyramid. The nature of this level is strongly dependent on the type of radiation being measured, the size of the particular user group at the fourth level, and the availability of a suitable third-level organization.

Occasionally NBS could be expected to bypass the third level and carry out traceability studies directly to the fourth level of the pyramid as a test of the overall system, but manpower limitations currently preclude much activity of this type.

Table 1 lists the present measurement assurance programs at NBS in the area of ionizing radiation, showing for each program the cooperating organization and the participants. In general, these are the third and fourth levels respectively, although this analogy is incomplete in a number of cases.

Table 1. Present NBS measurement assurance programs

Measurement application	Cooperating organization	Participants
Radiopharmaceuticals	CAP	medical labs
	AIF	manufacturers
	FDA	FDA
Radiation therapy	NBS (e-)	hospitals, clinics
	BRH (γ)	hospitals, clinics
Reactor effluents	NRC	NRC, States, reactors
Radiological pollutants	EPA	EPA, States, etc.
Radioactivity standards	ANSI	manufacturers
Reactor fuels and materials	ERDA	reactor labs

The first traceability study for radiopharmaceuticals was organized by the College of American Pathologists and took place in October 1970, when some 25 samples of iron-59, calibrated by NBS but unknown to the participants, were distributed for both radionuclidic identification and activity measurement. Since that time a number of additional radionuclides have been distributed to participating laboratories for identification and calibration under CAP auspices. An additional test was organized in which participants were asked to inject a known amount (on the order of 50 microcuries) of a solution of chromium-51 into a serum bottle and send it to NBS for verification.

The Atomic Industrial Forum and NBS have entered into an agreement whereby NBS supervises and administers a quality assurance program for the radiopharmaceutical industry. A research associate who is sponsored by the AIF is currently working full-time in an NBS radiochemistry laboratory preparing materials of relatively high radioactivities and toxicities. The first pairs of standards were shipped to industrial participants in April 1975, and 16 were supplied during the last year. The program has a built-in means to achieve traceability to NBS. Some of the standards are sent without certification and, upon receipt of a participant's analysis, the certified activity is supplied to him.

Several months ago an interagency agreement was completed between NBS and the Food and Drug Administration, Bureau of Drugs, that will provide the means by which FDA will maintain traceability to national measurement standards. Once a month NBS will provide radioactivity standards whose content will be unknown by the Bureau of Drugs. After the Bureau has identified the radioisotope and amount of it in the sample, NBS will provide the certified content and assist in improving the Bureau's analytical capability, if required.

Since 1967, NBS has provided a service whereby ferrous sulfate dosimeters are periodically mailed to users requesting assistance with absorbed-dose measurements in high-energy electron beams used for radiation therapy. The participants expose the dosimeters to between 5000 and 8000 rads (as measured in water) in a prescribed geometry at electron energies between 5 and 50 MeV. After irradiation the dosimeters are returned to NBS for spectrophotometric evaluation in terms of absorbed dose in water. The results are furnished to all participants. If a user's performance does not improve with repeated testing, NBS establishes personal contact with that participant in an effort to assist in eliminating problems.

For the past 2 years, the Bureau of Radiological Health has sponsored a program that tests the ability of therapy departments to deliver a prescribed absorbed dose of cobalt-60 gamma rays to water. Thermoluminescence dosimeters in plastic phantom blocks are mailed on a prearranged schedule to participants on a priority list established by BRH. The blocks are irradiated under prescribed conditions and returned to NBS for evaluation. Each participant is informed of his performance and, where applicable, suggestions are made for improving performance and dates for future retesting are arranged.

In the fall, a program sponsored by the Nuclear Regulatory Commission was initiated for the general purpose of improving the accuracy and reliability of measurements of environmental radioactivity and reactor effluents. Traceability to NBS is achieved by (1) testing of the NRC Reference Laboratory (ERDA Health Services Laboratory, Idaho Falls) to determine whether that laboratory is traceable to national standards within specified accuracy limits, (2) provision of standard samples and test samples for use in the States and the nuclear power industry, and (3) serving as a reference and referee laboratory to help resolve discrepancies in radioactivity measurements among States, government laboratories, and licensees. Through collaborative monitoring programs with the States and requirements placed on the licensee, the NRC obtains reasonable assurance that environmental measurements made by the licensee are valid, and that measurements made by the States and licensees are traceable to national standards.

A similar program was recently started under sponsorship of the Environmental Protection Agency. Its purpose is to have NBS develop standard reference materials for radiological pollutants associated with energy sources and production, and to conduct traceability studies with the EPA Reference Laboratory (Quality Assurance Branch, Environmental Monitoring and Support Laboratory - Las Vegas). During the next year, NBS will supply 200 calibrated samples of radium-228 at the 1 microcurie level. Occasionally, NBS will prepare test samples and special sources (e.g., gaseous standard samples), for distribution to the user level and to the EPA Reference Laboratory, all of whom will report analytical results to NBS for evaluation. NBS will also measure randomly-selected samples from an agreed number of "batches" of radioactivity standards produced by the EPA Reference Laboratory. Through these activities, the EPA quality assurance program, which provides calibrated samples and a variety of cross-check services to State, Federal, and industrial laboratories, will maintain traceability to national measurement standards.

In 1972, the Atomic Industrial Forum and NBS held a meeting of various manufacturers of radioactivity standards to consider the need for industry standards on quality assurance, statistics, and radioactivity. This led to formation of a group which is now known as ANSI Subcommittee N42-2, with the following general goals: (1) uniformity in reporting the accuracy of measurements of radioactivity standards, (2) conduct of a quality assurance program for manufacturers to include a round-robin calibration program under the sponsorship of NBS, and (3) developing and publishing recommended procedures for measuring radioactivity. During fiscal year 1975, five round-robin programs were conducted to provide measurement assurance for the manufacturers.

Neutron-induced reaction rates in fuels and materials for nuclear reactor design and safety present accuracy requirements which are demanding, approaching ±2 percent in some cases. By providing interlaboratory measurement coordination, reference fissionable deposits, and standard neutron fields, a program sponsored by the Energy Research and Development Administration and conducted by NBS will provide the measurement consistency and traceability required by reactor development technology. Without such measurement assurance, reactor fuels development and management, and reactor safety in general, face serious problems both in the area of economics and public acceptance.

In the area of nonionizing radiation, a laser power and energy measurement assurance program for 633-nanometer radiation has recently been announced. In this program a calibrated transfer standard is sent to the participant so that he can perform intercomparisons at his site. The measurement analysis is provided by NBS.

FUTURE MEASUREMENT ASSURANCE ACTIVITIES

It is interesting to note that all of the measurement assurance programs listed in Table 1 were inititated in response to national needs which were expressed during recent years. In many cases, the need was expressed by the cooperating organization, which itself was frequently responding to concerns expressed by other segments of our society. Even the program that shows NBS as the cooperating organization, namely radiation therapy with electrons, was requested by the American Association of Physicists in Medicine. Thus it has become apparent that there is a definite trend toward increased measurement assurance activities, particularly in those areas where the measurements are made for regulatory purposes. This is not surprising, in view of the fact that such measurements nearly always have substantial economic and public health implications.

If it is inevitable that meaningful traceability to national measurement standards shall be increasingly accomplished by way of measurement assurance programs, it would be desirable to have this occur in a planned manner. Therefore, NBS is currently involved in several studies of needs for future programs and methods for implementing them.

Since February 1975, NBS has been conducting a survey of needs for measurement and standards in State radiation control programs. This survey is now in its final stages, and it is planned to complete a report of the results in August 1976. A questionnaire that was recently distributed to all members of the Conference of Radiation Control Program Directors will serve as a primary source of information, supplemented by onsite visits that were made to 16 State programs. The Conference has collaborated with NBS in this survey and has established a Task Force on Radiation Measurements specifically for this purpose. It is expected that that Task Force will prepare a report by February 1977 on State needs, from the State perspective.

Based upon the survey results, NBS plans to initiate efforts that will satisfy the most urgent State needs, consistent with the NBS role and its limited resources. To gain experience in working with State programs, and to learn more about the best methods for efficient interaction, it is planned to begin working with a limited number of States, on the order of six. We will use as our guidelines the thoughts which were expressed by a State program director in response to the questionnaire when he said:

> "NBS should recognize that the typical State program cannot dedicate a large segment of either time or money to any aspect of the program without cutting out other aspects. We are not routinely interested in the magnificent accuracy or precision which might be the goal of NBS but rather an ability to measure, with reasonable confidence, levels of activity or radiation found in actual field situations and furthermore to be able to make such measurements with a minimum of efforts consistent with the nature of the operation being monitored, the risk involved, and the possible consequence of the measurement."

In the development of the basic national standards of measurement NBS is indeed interested in the highest degree of accuracy. However, in the conduct of a measurement assurance program, the NBS goal is not magnificent accuracy or precision, but is instead the same as the goal of the quoted program director, namely assuring with reasonable confidence that the accuracy or precision is adequate for the particular situation.

This implies a consensus among those making the measurements regarding what degree of accuracy is required for the various types of measurements. Based on a preliminary examination of the questionnaire responses, it does not appear that such a consensus exists among State program directors. Achieving this consensus might be a worthwhile next task for the Task Force on Radiation Measurements.

Although the survey in not complete, there is sufficient evidence on which to base the conclusion that a measurement assurance program is needed and wanted for radiation survey instruments, especially those used to measure x and gamma radiation. During the next several months, NBS will study the various alternatives for implementing a satisfactory program. The two alternatives to be given strongest consideration are regional calibration laboratories and a mobile radiation calibration laboratory. There is also appreciable interest in a measurement assurance program for thermoluminescence dosimeters. These devices have considerable potential for a variety of applications, but more work must be done to achieve reasonable confidence in their use.

For the past several years, NBS has collaborated with the American Association of Physicists in Medicine in the establishment and operation of regional calibration laboratories that are accredited by the AAPM. Three such laboratories have been accredited to serve as a link between the national standards and those making field measurements for radiation therapy dosimetry. Although there is general agreement that the radiation therapist needs a system which will permit him to deliver the desired dose to the tumor with an accuracy of ±5 percent, there is evidence that many irradiations are performed with much worse accuracy. In collaboration with the AAPM and the National Cancer Institute, NBS is studying the needs for more regional calibration laboratories and methods for achieving the degree of traceability that is required. One of the problems in this area is the lack of incentives for participation in a measurement assurance program. Incidents such as the recent "instrument error" at Riverside Methodist Hospital in Columbus, Ohio, which evidently went undetected for almost a year while 255 patients were overdosed, may do their part in providing the necessary incentives.

An additional future measurement assurance activity arose from a recommendation made by one of the workshops held during the Fifth Annual National Conference on Radiation Control. That group recommended that an impartial Federal agency, such as NBS, direct a continuing performance testing program that includes all personnel dosimetry services identified by responsible State and Federal agencies. A combined effort by interested Federal agencies is currently underway to develop standard criteria that will be used to implement a testing program that will insure reliability of personnel monitors. The Bureau of Radiological Health provided financial support to NBS for initial phases of the program and plans to promulgate the standard for voluntary adoption by users of x-ray equipment and non-NRC regulated radiation sources. The NRC plans to implement the program as a regulatory requirement for participation placed on its licensees.

PANEL: STATE EXPERIENCE IN HAVING AN OSHA AGREEMENT

Robert H. Wolle
Director, Divison of Occupational
and Radiological Health
Tennessee Department of Public Health

John R. Froines, Ph.D.
Director, Division of Occupational
Health
Vermont Department of Health

MR. WOLLE: I do not think that I am supposed to address the total problem or the whole situation of the States' experience with OSHA. I presume that you are talking about just the radiation aspects of the program, and I will confine my remarks and opinions to that situation.

It is not unusual for me to attend these meetings and come away confused. At my age and mentality, I sit in some of the workshops and task force meetings, and I do not comprehend what is being discussed. And I guess that situation was even more emphatic in early workshops I attended this week when I did not really comprehend what was being discussed. I looked up, and, they were discussing Workshop No. 5; I am working on No. 5. Then I happened to look back at the room placard, and I was at the funeral director's society; and the charge to the workshop was, "How to look sad at a $15,000 funeral."

Many of us sort of looked sad when OSHA came over the horizon. Many of us in industrial hygiene and radiation programs were very apprehensive about it; Tennessee no less than anyone else. But, I believe that since it has come over the horizon and we have dealt with it a bit, that we are not quite as sad.

I will discuss with you our opinions and our experiences to some extent. I think the way that we have been able to somewhat successfully accommodate the OSHA program as a portion of our radiation control program was facilitated by the fact that we began early following passage of the Federal Act. The Governor of Tennessee appointed the Department of Public Health a codesignee with the Department of Labor for the possible reassumption of the responsibilities that had been preempted by the Federal Act.

That put us in a bit of a unique position; there are some other States that are in the same codesigned position; I think Michigan, probably Colorado, and three or four others. We also have the industrial hygiene activities of the State and the radiation protection activities of the State in the same division, which, again, put us in a little bit of a different position from those States that perhaps had these activities in separate agencies. As a result, we in Tennessee, having had a fairly sizeable industrial hygiene and radiation program, and we thought a very good one, decided that we did want to be responsible, and reassumed these responsibilities for the OSHA Act as applied to Tennessee. We were among the first States to pass State enabling legislation. I think we were the first State to go operational under an OSHA-like program, which we call TOSHA, and to reach operational status in the development stage of the program. If everything goes well, we will reach the 18E determination stage, and the 18E certification stage, among the first States; probably about June 30 of this year.

Immediately after the passage of the Federal Act, therefore, we started development of a State plan. In the development of the State plan, because of OSHA's well known shortage of expertise in certain areas, they approached some States to provide technical expertise in making inspections and to turn the results of these inspections over to their people for enforcement. We were one of the first to provide this expertise, under a contract status. I presume some of your States have the same situation. We entered into a contract, and I think that some 8 of our people were put under a contract arrangement (100% of their salary funded through this arrangement). We retained, not like some other States, supervision of these people within our own house. Under this contract, they also asked us to provide a health physics type person. I guess this led to our eventual inclusion of the radiation section.

During this period, we provided a health physicist, along with the 7 or 8 industrial hygienists to conduct these inspections, until we went operational. When we started to contemplate writing a grant for operational status, since they had provided funding for a health physicist, we suggested that we pick this up as a part of our program, along with the industrial hygiene part of the program. They said, "fine." We went through a mathematical time study. One of our staff members estimated that approximately 60 percent of the time required for conducting field inspection work, performing calculations, and writing related to an occupational exposure. As you know, OSHA or TOSHA, can only apply to an occupational situation. We went through this computation, and we found that approximately 20 percent funding and approximately 3 staff persons could be added to our staff, plus partial funding of some of our supervisory staff as well as partial services of an attorney, an administrator, and a public information officer, which is part of our overall division staff. These could be obtained through this mechanism.

During this period, Tennessee was, perhaps, not as fortunate as some of you States, undergoing extreme budget restrictions. When you have been faced, as I was, with having to go to 4 members of your staff and tell them that as of a certain date, we no longer have funds for their positions, you are naturally looking everywhere for other sources with which to continue your staff.

Putting all of this together, we made a decision to implement a program of concurrent inspections under TOSHA in the radiaton area with our inspections of State regulations at the same time. I would be the first to say that this has not been fraught with great frustrations, headaches, staff complaints, and what have you. Many of the apprehensions proved to be true. Some of them proved to be not true, and some of them proved to be less of a headache than we had anticipated. Gerry first wanted me to present the "pro" side of the discussion, and I said I would do it, but would give a cavaet statement that the pro side did not contain my total views. We changed the aspect of the final version a little, but I will give some of the advantages and some of the disadvantages we have found in the program arrangement.

The major advantage that we have had, is the increased staff personnel due to the additional funding. At the same time, however, I would be the first to say that this has not been a net increase. The additional growth to our staff is offset by other matters which I will go into later.

The second big advantage that we have seen is an unquestionable increased degree of compliance. We find better, more timely response to citations and penalties than we did through our letters of compliance, by threatening hearings, rescinding the licenses, or restrictions and court actions. We find it a much more timely, effective mechanism of compliance. I think that some of it has also carried over into our compliance activities in the non-TOSHA area. As an illustration of this, we had a hospital in our State which traditionally when we made an inspection, after sending them a letter of items of noncompliance, we would get back about an 8 or 10 page letter with which the staff had to battle. The health physicist on their staff would tell us why our regulations were not right, why his method was much better, and we exchanged letters for a period of months, and probably by the time we went back for another inspection, we would still have items hung over. The last two times we made inspections of that facility (a large one with several programs), we got a letter back from the hospital administrator saying "Dr. so-and-so has been told to fix this according to the citation. Enclosed is our check." The next time we inspected the facility, the same thing happened. It has increased and enhanced the degree of compliance.

As a result of this, I have seen the staff gravitate towards using the TOSHA compliance mechanism in those areas where it is questionable; as for instance, in the Agreement States material area. NRC criticized our program in their last evaluation for doing this where there is a dual exposure. You have probably seen situations where both agreement materials and nonagreement materials are involved. In some of these instances, our people have gone to the TOSHA enforcement mechanism as a matter of choice. Our position is that we are in this business for enforcement, and the mechanism to get to that result is the one that we should use to earn our salaries for the benefit of the State and the citizens of the State.

I will also say that we find that some of the monitoring has its benefits. None of us like to be checked upon or having someone looking over our shoulder, yet we are monitored from top to bottom. In fact, we have a monitor that has a desk in our office and spends about a third of the time there, and about a third of the time in the field with our people. But fortunately, in our State, we have a very highly qualified individual performing this monitoring as it relates to the health aspects of the TOSHA program. He is very objective; he is professionally very well qualified, and we have had no problems at all with the monitoring. In fact, it has been a very effective additional management tool for us.

There are disadvantages, and I will not discuss the whole realm of them, but rather those that I see as the most pertinent. First of all, TOSHA or OSHA, covers only employees, and therefore it is necessary to conduct a dual State program to cover employers and the general public; this is a decided disadvantage. In no way could you carry out an effective radiation control program utilizing only TOSHA.

You also have to certify staff time, if you have an arrangement such as we established. It requires keeping numerous time records, which creates a lot of staff complaints. It requires the processing of two enforcement mechanisms in some instances, which is dual staff time loss.

Thirdly, although this has been a disadvantage, but not as great as we anticipated, there is the confusion of those who are being regulated for being faced with a dual regulation program. I credit it to the quality of the staff that we have not had that big of a problem in this area.

Fourthly, I think a major problem, and all of you recognize this probably even better than I, is the shortcomings of the OSHA regulations in the radiation area. They are very restrictive in their coverage and they are in some ways ambiguous or conflicting. There are conflicts between them and within themselves. The best illustration I know of is the requirements for signs. There are contradictions in certain parts of this section. Also, there is no differentiation for a restricted and an unrestricted area, and this leads to confusion in interpretation.

I think the shortcomings in the regulations are a very great disadvantage. I would say unequivocally that it is absolutely impossible to carry out a radiation program under TOSHA alone. I am not saying that it is everybody's cup of tea, but in Tennessee we have found it to be a palatable one. I believe, and as Chairman Will stated at the beginning of our session, we are all regulatory agencies, and enforcement is the bottom line. This very important advantage of increased, enhanced enforcement has made it one from which I believe the program in Tennessee has received some benefits.

DR. FROINES: Last year at Hyannis, Bob, myself, Gerry and some others were having a discussion about OSHA. At that time, we were quite critical of OSHA and what we considered to be its rigidity, its lack of imagination, and its general bureaucratic nature. This panel has arisen from that discussion.

Some time during the year, Gerry called me and asked me if I would speak about our experience with OSHA, and I agreed. And I said, "What would you like me to talk about?" He said, "Highlight the positive aspects, and highlight the negative aspects, but be very sure to highlight the negative aspects."

The problem, to be a little self critical, is that in the last year I have learned a great deal, and feel much less critical than I did. In addition, I think that OSHA has matured. In a sense, what Bob Wolle just said really echoes what I want to say.

At this point, I think that there are fundamental problems with the Occupational Safety and Health Administration, especially in the health area. But in terms of my own experience, our experience in Vermont, I must admit that I have developed a more positive view, and have reevaluated some of the questions that we had last year.

Last year, there was an industrial carcinogen meeting in New York City sponsored by NIOSH, the New York Academy Sciences, and the National Cancer Institute. At that conference there was one paper on radiation as a carcinogen associated with uranium miners in Colorado. In other words, at one of the most important conferences on industrial carcinogens ever held in this country, there was really no commitment to looking at radiation as a carcinogen, particularly in an industrial environment.

This is a serious problem that runs through OSHA and NIOSH. At the same time, I was thinking about this talk today, I went through the program of this conference for this year, and I thought back about the program last year, and I do not remember from last year nor from this year, any papers, besides perhaps these, that deal directly with radiation as an industrial carcinogen. There are no papers at this conference that deal with occupational exposure to radiation, as far as I am aware. And so we all bear a burden of criticism with respect to OSHA and from our own side. There is a kind of gap that has been created, and I think is being perpetuated and enlarged. I would hope in the future that we take a clearer, closer look at this problem.

What happened in Vermont was quite different from what happened in Tennessee, and from talking to Bob Will in Washington. In Vermont, we had two persons in our State OSHA program who were doing x-ray inspections under the Occupational Safety and Health Act. The regional administrator from OSHA in Region I, Boston, came and said that they would no longer fund these inspections. We were forced to drop that program from our State program because the Federal Government would not fund it. I am not raising the point about the fact that they forced us to drop it; they used the funding mechanisms to do that. Their criticisms were that the radiological program was basically a public health problem; it was not an occupational health problem; therefore, OSHA would not fund it. I do not agree entirely with that view. There are employees who are exposed to radiation in doctors offices, in dentists offices, in hospitals, and what have you. In fact, there is an occupational problem. However, there is also some truth to the question that most of our efforts really were directed toward protection of the patient, and that we were guilty of using the occupational exposure as a way to obtain funding. In a sense, there was a kind of duality associated with our own approach. OSHA in Region I decided that they would not fund it. In Bob's region, they decided that they would fund it. In Washington, they funded it, apparently, but with some limitations. One of the major criticisms I would like to make is not whether or not OSHA should fund an x-ray program in a State occupational safety and health program, but more importantly, that OSHA lacks any sense of national direction with respect to this question. That is really the issue that we have to deal with in the long run.

I am not too concerned about whether the State pays 100 percent or whether OSHA pays 50 percent. The problem is what we really need with respect to OSHA in this country is a direction, a sense of how they are going to go--not only with respect to Tennessee in their region, but with respect to Vermont, and so on. I think that is a problem, and I think it came from of a real lack of leadership in Washington. I think it is changing but decision making has been left to the regions, and therefore created confusion for us all. The problem, it seems to me, still exists. There has been no fundamental change. I should say I am glad that OSHA is not funding us, because what that does do for Vermont is leave us the options to run our own programs as we so choose tc. There are some advantages to that and there are some disadvantages in terms of its cost, but the advantages outweigh the negative aspects.

The second major criticism I would like to make of OSHA is more or less a restatement of what I just said. We hear, from a number of sources, including President Ford, that there are approximately 100,000 deaths per year from occupational disease; however, we hear literally nothing from OSHA with respect to radiation as a carcinogen. There are no attempts to develop broad base operational standards with respect to radiation, especially with respect to radiation as a carcinogen. It is fair to say, however, that that criticism should not be left to radiation, because as many of you are aware, OSHA's ability to set standards for occupational health has been nil, except for asbestos and fourteen carcinogens. The point I am trying to get at is that with respect to radiation, there has been no attempt to develop comprehensive standards which would be enforceable throughout the United States. Having made that criticism, and I make that criticism as strongly as possible, I must add there has been a change in the national leadership. Dr. Morton Corn is now the director of OSHA. He is a person who is very health oriented, and I think that at this point, Dr. Corn needs positive and programmatic input. I would argue that perhaps one of the tasks of this conference would be to set up a task force or committee that would relate to OSHA in terms of future standards setting and in terms of developing a relationship between ourselves and OSHA with respect to OSHA's program in the area of radiation. I think that would benefit this conference; I think it would certainly benefit OSHA; and there is no question that ultimately it would benefit the employees in this country who are exposed to radiation. At this point there is a director in Washington who would be sympathetic to that.

I want to close, and not go into the details, about the specifics of our program in Vermont. We can talk about that more informally, if you are interested. I want to finish by saying that I think that we are in a period of time when everyone from the President of the United States down is very critical of regulatory agencies, and I think that OSHA is probably, if not the most criticized, certainly one of the most criticized regulatory agencies in the United States. I do not think that criticism is going to diminish. There are 38 bills in Congress right now to amend OSHA or to abolish it. As you well know, when President Ford was in New Hampshire, he said that he would like to throw out OSHA altogether.

The Division that I administer in Vermont has a 38-year history of industrial hygiene. We are staffed with highly qualified people; we have excellent contacts with universities throughout the region. We have a very strong program, and historically have had a strong program, but I would be willing to argue at this point that that program historically has been ineffective, even though it has 38 years of experience. The program was ineffective because it lacked an enforcement mechanism. I think that is what OSHA has brought to enhance our efforts. Enforcement capability has the mechanism which we needed and should maintain and strengthen.

In a period of time when there is terrific criticism of enforcement agencies, that is, regulatory agencies, we have to rededicate ourselves to the idea that we are in the business of enforcement; that our constituency is not those we regulate, but are those that are exposed to toxic substances and radiation. That is, our constituency is employees and the public, and that enforcement, coupled with consultative services, is a fundamental aspect of achieving our important mission of providing a healthier workplace and should be maintained. I think that, with all the faults, OSHA has made a very serious attempt at maintaining that mission and through criticism and pragmatic suggestions, we should join them in their efforts.

DISCUSSION

MR. KERR (NRC): I feel like I need to make a few comments because of the statements Bob made in connection with our review of their program, some possible conflicts with OSHA, and the enforcement mechanism of the State program. There are three points I want to make. The first is, I am a firm believer in clear jurisdictional lines, and I think the jurisdictional lines are reasonably clear, with a couple of fuzzy areas, between OSHA and us. OSHA has a clear exemption for Agreement State licensees, and we think it should be kept that way. Second, we hear of a large variety of differences between the OSHA, as being applied from the regions, I take it, and the various States. If you talk to Bob Wolle, Bob Will, Al Hazle, and Heyward Shealy about the details on how OSHA is implemented in their State, they are quite different.

And the last comment, is about Bob Wolle's comment about fines, where he indicated that the guy willingly sends the check in this time, and the next time they go back, he sends another check; I guess that just raises the question, are you achieving compliance, or are they being intimidated by the check, and was the other enforcement mechanism not pursued far enough to achieve compliance? If your position is correct, you should be willing to take stronger action, rather than continue to send letters.

MR. WOLLE: I did not mean to imply that the checks were for a repeated offense. If it had been, it would have been a much steeper fine. We find that we get that problem eliminated. We find that was not true under our former enforcement procedure. I will restate that we find a more increased enforcement procedures. There is a line of demarcation between Agreement States materials, and it is not our intention to have them overlapping; however, we do have a little disagreement as to where the line of demarcation is where there is dual exposure.

MR. WUKASCH: John Froines mentioned something about the political implications and the effect on OSHA. If any of you have not read today's current issue of Time magazine, I would like to recommend it; there is a very interesting article in there. Do try to read it; I think it is a very informative article, and it showed a lot of the difficulties OSHA has had and some of the bobbles I think they have made, which I think are very accurately reported.

MR. WOLLE: I would also, at the same time, recommend you read the last week's issue of the Wall Street Journal. It reported that there was a complete reversal of employers in polls who had been inspected by OSHA, compared to those who had not, as to its opinions as to whether it should be abolished, and whether it is an effective agency or not. The polls were competely reversed. I think a good many of us have experienced that. There have been many articles that I agree with about criticism of OSHA, and I would like again to put in a cavaet statement, and share in Dale's opinion, in many respects.

MR. FROINES: I think that one of the things that is occurring in the country at this point, and even up to Dr. Corn, is that there appears to be a renewed emphasis for what we might call voluntary compliance, or consultative type programs. Certainly, President Ford's budget illustrates that new emphasis, and Dr. Corn has talked about it, and throughout the country there is a push for it. I think that I am personally not opposed to the idea of a consultative program, or a voluntary compliance program, but I think ultimately they are ineffective and they do not work. I think, basically, that they represent the same kinds of programs that existed before the passage of OSHA, which required the passage of OSHA in the long run; that OSHA finally was passed precisely because there were weak State programs that were precisely consultative in their nature. I think in this period of time that one can achieve voluntary compliance, that one can develop excellent consultative programs, but only in the context of having an equally strong, even handed enforcement program.

MR. VAN FAROWE: Looking at the history of enforcement of occupational health programs in the past, I think that we can clearly see that the employees themselves do not have an interest in the protection of their own health, and neither did the union at that time. I can recall many situations that we go into in Michigan where we would find situations where the toxic materials in the air would be above the standards that were set, but both the employees and the unions were willing to bargain for an extra 25¢ an hour as a corrective measure. So it was a benefit/risk ratio, I guess; they were willing to accept the risk, if they could derive a greater benefit from it. Now suddenly, we have seen a swing in the other direction, as a result of government intervention, and I am not sure that enforcement by government is the solution to the health problems when we are in a risk area. If it is a clear black and white situation, where you have a speed limit, you assess the fine, and you have a police state as a result of that particular activity, I think that is one matter. However, when we are into the grey area of health, and we just really are not sure what these limits should be, then we assess fines, we are developing a police state throughout the entire government. I think that this may be a greater jeopardy than the slight health hazards that may result from overexposure.

MR. WOLLE: I presume that the model regulations are protective, and I presume that they should be enforced. I think that that is one of the problems, with which we should be very cautious. Regulatory agencies, I think, are going to have to look very carefully at their regulations and their development and content and their staff in the light of this. I think that is one of the things that has led to the criticism of regulatory agencies. I think that persuasion and education, certainly, can go a long way; however, I have had some experiences in which it does not go a long way. We have had more problems in Tennessee with industry than with licensees and registrations. It is not confined to industrialized areas. When I relate some of our experiences with some of our industries running off and leaving problems; some of them associated with very well thought of associations. They say that we are surprised that things like that happen down in Tennessee; we thought it happened up in New York and other places. I think that there is a need for enforcement, and there is a need for consultation and training and education; and I think that what Mr. Van Farowe said is certainly very true. But I think we really should look at our passing of these regulations and these standards. They have a far-reaching effect; if we really believe them and collect our salaries in enforcement, we must be very careful in their conduct and impact.

MR. FROINES: I want to describe our experience with a thermometer manufacturer in Vermont. They employ 125 people; most of them are women; some of whom are pregnant. We found that approximately 100 our of the 125 employees in that plant were exposed to levels of mercury that were 12 times over the limit value. Now, there were serious problems of mercury poisoning in that case. That plant owned a mercury vapor sniffer; that plant had been visited by our Division for 5 years, and nothing during that 5 years had ever been done to abate the problems that existed in that plant. There were people who have mercurialism in that particular plant. Under VOSHA, they were cited and fined, and they have since put a $25,000 ventilation air recirculation system in, and I would be willing to argue that that would never have occurred if there had not been an enforcement mechanism. I could list hundreds of examples. We required this mercury vapor plant to issue respirators to the employees during the time that they were putting in the ventilation and air recirculation system. That employer states that he did not want to provide respirators because the employees might think that there was a problem of mercury in the plant and make them concerned. I think it is true; I think very often, particularly in times of recession when there is 8 percent unemployment, people will trade off their health for their wages, and I would too under the same circumstances.

Very often, we exist in situations where employees have no idea to what degree they are exposed and to what they are exposed to. So there is a terrific education problem required. We have all sorts of educational and consultative programs for management; we have very few, if any, educational and consultative programs for employees. I think we need them, but I think that to try and be positive about that, with respect to the whole question of standards, which is a very tricky area, it would behoove this conference to try to make an attempt to participate with OSHA in developing proper, good, enforceable standards.

WORKSHOP NO. 1

GUIDELINES FOR SURFACE CONTAMINATION LIMITS APPLICABLE TO UNRESTRICTED USE BY THE GENERAL PUBLIC (EXCLUSIVE OF LAND SURFACES)

Sherwood Davies, Chairman, New York
James E. Blackburn, Illinois
Frank Bradley, New York
Dayne H. Brown, North Carolina
Art Huebner, Connecticut
Ellen G. Haars, Iowa
Bill Graham, Tennessee
Ted Wolff, New Mexico

Wayne Kerr, NRC
Lauriston Taylor, NCRP

Workshop No. 1 participants considered the general category of radioactive contamination and the limits adopted by various organizations. We have developed recommendations for presentation to the Conference.

TYPES OF RADIOACTIVE CONTAMINATION

Radioactive contamination of materials, products, equipment, areas and surfaces may result from routine uses of radioactivity, accidents, and intentional or unintentional introduction of radioactivity into materials.

Our review was limited to surface contamination resulting from accidents or routine uses of radioactivity. We did not consider nor do our recommendations suggest applicability with respect to clothing, bodily contamination, prosthetic devices and consumer products which may either be intentionally or unintentionally contaminated with radioactivity.

Our review of the limits has been predicated upon health considerations. The use of premises or materials in connection with activities such as a low level counting laboratory, or the manufacturing and storage of undeveloped film may require limits more stringent than health and safety considerations. Additional requirements concerning appropriate limits are considered to be the responsibility of the operator.

Consistent with long standing practice in the radiation protection field, it is prudent to reduce any radioactive contamination to a level as far below the numerical guidelines as is reasonably achievable. Based upon public health considerations the most restrictive limitation would be occupancy of a private residence.

SURFACE CONTAMINATION LIMITS

The workshop reviewed the following documents relating to surface contamination limits.

1. Draft ANSI report "Control of Radioactive Surface Contamination in Materials, Equipment and Facilities to be Released for Uncontrolled Use" dated December 1975.

2. U.S. NRC Regulatory Guide 1.86 "Termination of Operating Licenses for Nuclear Reactors" dated June 1974.

3. U.S. NRC draft "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for By Product, Source or Special Nuclear Material" dated December 1975.

4. New York State Department of Health "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Radioactive Materials" dated October 1974.

5. New York State Department of Labor regulatory limits in Industrial Code Rule 38.

6. U.S. NRC regulation 10 CFR 140 "Financial Protection Requirements and Indemnity Agreements."

With the exception of 10 CFR 140 Regulations, the surface contamination limits referred to in the above documents are not significantly different and compliance with the upper limits of the above mentioned guides would present no undue hazard to life and health. Nevertheless, the workshop participants strongly urge that surface radioactive contamination be reduced to levels "as low as practical."

The ANSI report provides the empirical evaluation of the derivation of numerical values based upon health considerations.

Except for 10 CFR 140, the workshop recommends that any of the above mentioned guides be considered acceptable until a nationally accepted standard is adopted.

In the application of these surface contamination limits further evaluation of external gamma radiation and airborne concentration of radioactivity may be needed.

SUMMARY

The workshop participants recommend the following:

1. That with the exception of 10 CFR 140 limits, anyone of the above mentioned surface contamination guides could be adopted either as a guide or standard by the State or Regulatory Agency.

2. That professional judgment must be exercised in the application of these guides.

3. That the workshop on Surface Contamination limits not be continued as a Task Force.

4. That the Executive Committee prior to the 1977 Conference determine the need for convening another workshop on surface contamination limits.

WORKSHOP NO. 2
GUIDELINES ON SURVEYING A MEDICAL ACCELERATOR

Edgar D. Bailey, Texas, Chairman
William H. Aaroe - Philadelphia
Michael H. Mobley - Tennessee
Hal S. Stocks - Indiana
Lawrence J. McDonnell - Wisconsin
John Giedt - North Carolina
Coleman H. Smith - Oklahoma
John Russo - New Jersey
James E. Hickey - Rhode Island

Sherman Fivozinsky - NBS
Robert Jacobs - BRH
Lloyd M. Bates - AAPM - Guest

Primarily, linear electron accelerators and betatrons, and to a lesser extent the Van de Graaff, are the types of accelerators being used for medical therapy today. The use of the cyclotron and Cockcroft-Walton type accelerators has been limited to a few research-oriented institutions, and therefore were not considered by the Workshop. The considerations outlined below are in addition to those normally encountered in therapy inspections.

In surveying medical accelerators one may expect to see linear accelerators and betatrons with energies ranging up to 50 MeV and Van de Graaffs with accelerating potentials from about 500 KeV to 3 MeV. Almost all of these machines use the x rays produced from a metal target or the electron beam itself as the direct treatment modality. In surveying a medical accelerator, one must consider not only the high energy electrons and photons, but also photoneutrons that may be present in the primary beam and in the leakage and scattered radiation for machines operating above 10 MeV.

In addition to these obvious radiations, one must be aware of the possibility of some subtle hazards that may co-exist. These include:

a. Induced activity in components of the accelerator and treatment room (this may raise the question of licensure or exemption of these radioactive materials).

b. The presence of depleted uranium shielding in some accelerators.

c. The microwave or RF fields associated with acceleration of the electrons in the case of linear accelerators.

d. The presence of laser beam alignment and positioning devices.

e. The presence of ozone and radioactive gases generated in the treatment room by the radiation beams.

Two areas must be evaluated in a complete radiation survey of a medical accelerator facility:

1. The area outside the treatment room must be surveyed for photon radiation and in the case of accelerators operating above 10 MeV, for neutrons. State inspectors should verify the survey of this area during routine inspections with currently used ionization-type survey instruments supplemented. Ideally, with a neutron rem-dose instrument.

2. Within the treatment room, tube head leakage and primary beam parameters must be determined. This survey/calibration should include assessment of both the photon and particulate (i.e., electrons and neutrons) components of the radiation fields. These measurements are technically difficult to perform, require instrumentation not normally found in State programs, and involve duplication of effort. Since the medical accelerator facility conducts these surveys, it seems inadvisable to have State inspectors repeat these measurements during routine inspections. These surveys must be reviewed by the State regulatory agency.

Each State should require all medical accelerator facilitities to submit proposed plans and technical specifications for review prior to commencement of construction. Upon completion of construction and/or installation, but prior to the initiation of a patient treatment program, the facility should perform a radiation survey of the facility to determine its adequacy and adherence to facility design specifications and machine performance standards. This survey should be submitted to the State regulatory agency for review.

At the present time the review and evaluation of facility design plans and radiation surveys are hampered by the lack of NCRP-type reports specifically addressing medical accelerators operating above 10 MeV. States must now rely on manufacturers' specifications, assorted technical books and papers, and reports on similar type facilities (if available) to make their evaluations. These evaluations are also confused by the lack of a nationally-recognized acceptable tube head leakage rate for neutrons.

RECOMMENDATIONS:

The Workshop recommends:

1. That the Conference urge BRH to promulgate a performance standard for medical accelerators. Standards on leakage radiation and beam monitoring systems are needed immediately.

2. That the Conference encourage the development of an NCRP-type report on medical accelerators operating above 10 MeV.

3. That the Conference and BRH, in concert with professional organizations such as AAPM, develop survey procedures, codes of practice, and protocols adequate to satisfy regulatory requirements.

WORKSHOP NO. 3

METHODS FOR ACHIEVING SUPPORT FOR YOUR STATE RADIATION CONTROL PROGRAM BUDGET

Aubrey Godwin, Chairman, Alabama
Jim Borg, Louisiana
Melvin O. Nelson, South Dakota
Margaret Reiley, Pennsylvania
Heyward G. Shealy, South Carolina
Dave Lacker, Texas
Donald W. Hendricks, Nevada
David Johnson, Wyoming
Phillip D. Babb, Kentucky

Sheldon Schwartz, NRC
John Boesen, BRH
Ralph Bunge, BRH

This workshop report will not try to answer the question of which budgeting technique is best. In fact, the technique usually is not selected by the radiological health program, but is mandated by other State constraints. Justification of a program budget is a year-round process highlighted by formal submission of a budget request once each year, or every other year.

It is agreed that program support is dependent upon achieving and maintaining program visibility. This visibility must be obtained within the internal system, the executive administration, the legislature, and the public. To show a positive effect, visibility must be credible. Program achievement helps obtain credibility.

This report will look at several techniques and extract aspects of each of these which have proven to be useful in preparing and presenting radiation control program budgets. Techniques which we identified in the workshop were: zero based budgeting; management by objectives; cost/benefit; status quo; and SWAG.

RECOMMENDATIONS

This workshop recommends that a task force not be established on this topic; however, the Conference should establish a clearinghouse for the exchange of such information. Benefit derived from such a clearinghouse could be the development of model justification for specific program areas.

(Also at this Conference, but not as part of this workshop, we had an ad hoc meeting on Emergency Planning. We met with NRC on several things; there were seven States involved. In summary, we recommend to the Conference and NRC that there be some delay in developing further task force reports until there has been some agreement on what is actually the basis we should develop our emergency plans to; that there be a review of the concept of encouraging the State emergency plans; and that the Executive Committee of the Conference appoint a committee or task force to work with NRC in the overall development of guidance for study and that they disseminate the information to the States and they use the Conference Newsletter in the dissemination of this information; and that the Conference request the agencies that require the development of guides be encouraged to develop that guidance in a timely manner.)

WORKSHOP NO. 4

ESTABLISHMENT OF SOIL CONTAMINATION LIMITS

Al Hazle, Colorado, Chairman
Ulray Clark - Florida
Wallace Johnson - Florida
William Betz - Ohio
Marshall Parrott - Oregon
Tom Cashman - New York

Richard Guimond - ORP/EPA
Elmer Eisenhower - NBS
Bill Baumgartner - U.S. Testing Co.
Craig Roberts - SD/NRC
Edward Held - SD/NRC

The scope of this Workshop was identified to evaluate the feasibility of establishing guidance for soil contamination limits for long half-life radioactive material. Also predetermined was that such guidance under this topic excluded mining and milling operations. The Workshop has been requested to identify those situations where such limits are needed and to rank them in order of priority. Additionally, the workshop was to examine the relative feasibility of establishing such guidance and, on the basis of existing information, determine the most feasible situations for development of the respective guidelines.

It was determined by this group that such guidance be limited to unrestricted offsite situations keeping in mind that restricted onsite levels may have a significant impact on lands more remote.

Following detailed discussion, the Workshop identified the following items as particularly important with respect to their potential for causing soil contamination of radionuclides.

- Operations and decommissioning for:

    (a) Nuclear fuel cycle facilities including nuclear power stations.
    (b) Federal facilities including military installations.
    (c) Other regulated facilities handling radioactive material.

- Non-nuclear facilities:

    (a) Fossil fired and geothermal electric generating plants.
    (b) Bauxite, rare earth processing opertions, and so forth.
    (c) Water treatment residue disposal.

- Natural geological formations:

    (a) Phosphate deposits.
    (b) Uranium and thorium deposits.

The long-lived radionuclides of greatest concern were identified in order of their importance based on anticipated potential population dose, emotional concern and possible health risk.

A. Plutonium.
B. Radium (and its short-lived progeny).
C. Mixed fission products (greater than 20-year half-life).
D. Transuranic elements.
E. Polonium.

To establish a reasonable guidance for soil contamination, the following evaluations are essential:

- The acceptable level of biological effect or health risk (somatic and/or genetic) must be identified. This is a most critical criterion and must be chosen with a great number of variables subject to controversy. This selection must include a cost/benefit analysis for each of the cases addressed.
- Conversion of these health risks to a reasonable estimate of radiation dose to the respective organs of reference.
- Conversion of the radiation doses to inhalation or ingestion concentrations.
- The relationship of inhalation and/or ingestion concentrations to soil contamination levels.

Numerous specific assumptions will be necessary in order to arrive at suitable soil contamination guidelines. All such assumptions incorporated in the guidance must be clearly identified and justified. Each radionuclide, its present and future environmental chemical forms, anticipated land use (present and future), and geographical location may present situations substantially different from that used in specific guidance development. Therefore, the guidance "limits" selected may require modification on a case-by-case basis to properly adjust for environmental parameter variables.

Any guidance developed should carefully consider whether the guidance is to be applied (a) prior to any contamination, and/or (b) after contamination has occurred. In addition, since this issue is complex from technological and political standpoints, extreme care must be exercised in the development of such guidance.

RECOMMENDATIONS:

(1) That the Conference establish a task force to address this topic. The membership of this group should include States that are already involved, and Federal agencies directly or indirectly impacted, including but not limited to ERDA, NRC, DOD, EPA, USGS, BIA, and DOT. Additional expertise in areas not common to the above agencies must also be made available and used.

(2) That the Conference strongly urge EPA to finalize at the earliest possible time complete guidance on plutonium in soil.

(3) That the Conference task force critically review all international and national standards and guidelines on this subject as such information becomes available and report to the Conference their findings.

(4) That the task force establish an action plan for the development of necessary (interim or final) soil contamination limit guidance (prospective and remedial limits and monitoring techniques) and that priority be given to plutonium,, radium, and other long-lived materials.

Additionally, consideration be given to other radioactive materials regardless of half-life and/or industries as their deliberations identify.

WORKSHOP NO. 5

REVIEW AND EVALUATE THE NEED FOR AND CONTENT OF ANNUAL STATE RADIATION CONTROL PROGRAM REPORTS

Donald E. Van Farowe, Chairman, Michigan

The workshop was charged with the responsibility of reviewing and evaluating the need for the content of reports of the State radiation control programs as requested by the Federal agencies. As you are aware, the Food and Drug Administration questionnaire, received annually by all of us, has not been updated or evaluated in recent years. In addition, during this period, several other Federal agencies, such as EPA, NBS, and NRC are also beginning to request data through the questionnaire process. Our primary goal is to collectively analyze the needs of these agencies and simplify the process.

We agreed that in the time alloted we could not complete the construction of the detailed draft questionaire, but could set forth the general areas of interest represented by each of the Federal agencies requesting information.

In our deliberations, we found that the interest of FDA falls into the following areas: (1) basic expenditure information by program areas; (2) a person-year equivalent by program areas; (3) information on x-ray control program activities; (4) information on particle accelerator program activities; (5) information on radioactive materials program activities, particularly as it applies to naturally occurring and accelerator produced radioactive materials; and (6) information on other radiological health activities, nonregulatory in nature that have to do with user educational programs, special studies, symposia, and so forth.

Similarly, in talking with EPA, we found that their interest falls into the following areas: (1) basic expenditure information for environmental surveillance; (2) ambient monitoring activities; (3) source monitoring activities; (4) environmental nonionizing activities; (5) emergency response planning; (6) personnel monitoring and recordkeeping; (7) nuclear facility siting; and (8) natural radiation.

These two agencies implied that their interest relates to continued need to be cognizant of States' activities and needs in order that they be placed in national perspective in regard to Federal programs. In addition, we discussed briefly the requirements of the Nuclear Regulatory Commission with which Agreement States are aware. Certain elements of information required by NRC must remain in present format; however, the Commission has agreed to allow certain statistical elements of information to be transferred to the draft questionnaire. We also considered a possible request from the National Bureau of Standards for data to be included.

Finally we discussed requirements of the States and agreed that the information being acquired should be of a nature that would be useful to all Participants, both Federal and State.

CONCLUSIONS

1. The present FDA questionnaire requires information that is no longer utilized and should not require additional data.
2. Presently, the States are requested to complete questionnaires from several agencies.
3. Similar information is requested from different sources and different contexts therefore invalidating any honest comparison of answers.
4. There is an obvious need for some duplication and subsequent combination of the inquiries into a single form.
5. There is an imperative need for the establishment of a common base of questioning so that the information will be useful to all participants.

RECOMMENDATIONS

We recommend the establishment of a drafting committee and an editing committee; the former to be comprised of representatives of Federal agencies and the latter to be comprised of the State representatives in this workshop. Given that premise, we further recommend the following:

1. The drafting committee convene and work on a rough draft questionnaire within the next 60 days to be mailed to the editing committee.
2. The editing committee return their comments independently within the following 30 days.
3. Upon receipt of the comments from the editing committee, the drafting committee will reconvene to develop the final draft. It is to be resubmitted within 2 weeks to the editing committee for final comment.
4. The editing committee will return their minor comments to the drafting committee within 2 weeks, completing the entire procedure within a 120-day period.

WORKSHOP NO. 6

STATE/FEDERAL RELATIONSHIP FOR ENFORCEMENT OF P.L. 90-602

Richard Lane, District of Columbia, Chairman
Anthneil Thompson - Maryland
Eddie S. Fuente - Mississippi
Pedrito Francois - Virgin Islands
Tom Gerusky - Virgin Islands
R. Woodruff - Alabama

Herbert Klein - FDA
Robert G. Britain - FDA
Richard Cooke - FDA, Region V
H.S. Boyne - NBS

Scope

To explore means and methods of improving the working relationship between State and Federal programs as they relate to enforcement of the Radiation Control for Health and Safety Act of 1968.

Objectives

1. Define problems in Federal/State relationships in enforcement of existing standards and recommend workable solutions.

    A. One of the problems in Federal/State relationships in enforcement of standards appears to be communications relative to survey results. State should receive copies of letters of noncompliance to assemblers and copies of field test results.

    B. States who have not provided for compatibility of regulations P.L. 90-602, should consider a mechanism for initiating the provisions covered under this law.

    C. FDA does not always provide the States with information relative to the effectiveness and completeness of recall. FDA representatives gave assurance that procedures will be established to supply this information to the States.

    D. BRH will examine the possibility of joint participation between BRH and the States in the inspection of manufacturers. Violation of the manufacturer's rights to proprietary information may be the limiting legal factor.

2. To develop a system which will take care of compliance problems with the diagnostic x-ray performance standards by State inspectors during x-ray inspections as smoothly as possible.

    A. Under new FDA contract provisions, a specified number of inspections will be completed by the participating States. This will allow the use of contract personnel for verification of voluntary corrective actions initiated by RRHR and the RCO with the local distributor and dealer or assembler.

B. It is recommended that non-contract States when conducting routine surveys and encounter certified x-ray units and/or components, and identify items of non-compliance, report them to their BRH regional representative. A cooperating State should receive information relative to the assembler or manufacturer correcting the deficiency.

3. Evaluate impact of the Laser Standard and proposed draft standards of Federal/State working relationships, identify projected problem areas (such as lack of legislative authority), and develop recommended action programs for Federal and State agencies.

A. Discussion relative to the impact of laser standards was deferred until the members have had an opportunity to review the final draft of the Council of State Government regulations.

B. It is the opinion of members of the Workshop that the States will eventually be required in some degree to become active in the nonionizing radiation areas. This pressure will result from continued promulgation of Federal performance standards being enforced. The State legislation may require amending to include nonionizing radiation and, if necessary, model State regulations should be developed in the laser and other nonionizing radiation areas.

The immediate State deficiencies are in the areas of education and instrumentation.

C. Proposed action of States:

(1) Registration of lasers, and other nonionizing radiation as deemed necessary.

(2) Accident reporting requirements.

4. Review the advantages and disadvantages of compliance inspection under Federal contracts (reimbursable) as opposed to State voluntary compliance inspections in the enforcement of FDA regulations.

It was the general consensus of the Workshop that the advantages of Federal contracts far outweigh the disadvantages. Under the present financial system, States are reluctant to compromise regulatory efforts (reduced inspections) without a monetary return for work performed.

5. Consider the pros and cons if State personnel were "commissioned" as a Federal officer for the purpose of conducting examinations, investigations, and inspections under P.L. 90-602.

We should have additional information regarding commissioning of State people. One area which stands out is the need for training State personnel. We lack experience in dealing with the Federal judiciary.

Though persons involved in Workshop No. 6 were able to solve some day-today problems, we find no need for the continuation of the Workshop. It is felt that forthcoming problem areas can and will be solved on an individual basis.

WORKSHOP NO. 7

INFORMATION NEEDED TO EVALUATE PUBLIC HEALTH IMPACT OF NUCLEAR MEDICINE PRACTICE

Gerald W. Allen, Chairman, Kansas

The deliberations of Workshop No. 7 were based on the observation that a number of authors from various disciplines have reported an increasing utilization of nuclear medicine procedures; while a number of studies and local experience where very broad parameters were reported, there appeared to be nothing upon which to base judgments on the nationwide utilization of nuclear medicine. To describe recent changes in the development of procedures, it seemed reasonable to expect accurate predictions of the near future impact of nuclear medicine on such things as population dose.

In attempting to achieve the objectives established by the workshop, it was determined that the collection of statistically significant and nationally projectable nuclear medicine data from randomly selected number of facilities is needed. The following were noted:

1. The availability of sources of information on nuclear medicine practice in the United States include but are not limited to the "Survey of the Use of Radionuclides in Medicine, 1966" BRH/DRME-70-1. While probably having the necessary scope, this document was produced in 1966, prior to the event of the molybdenum-technitium generators.

2. "The Estimates of Ionizing Radiation Dose in the United States,1960," EPA/ORP. The data specific to nuclear medicine was very brief and appeared to be lacking in depth necessary to be useful for an evaluation of new developments such as the computed tomography units.

3. Numerous other studies by the BRH, Joint Commission for Accreditation of Hospitals, the American College of Radiology, and others were developed for specific purposes or with limited samples and appeared not to be suitable for predicting management trends.

One approach to collecting the needed data utilizes the Food and Drug Administration's Medical Oriented Data System (MODS), which is very limited in scope. It was decided that if this system could be expanded to provide us statistically significant data, a number of useable outputs would be expected, including but not limited to: (a) most frequently used radionuclides in procedures; (b) most frequently used doses by procedures, age, sex, and so forth; (c) equipment used; (d) repeated procedures; (e) procedures leading to conclusive results; (f) annual contribution of nuclear medicine procedures to the population dose.

It was noted that the type of data decribed above might be comparable in information content to the data collected from the Nationwide Evaluation of X-Ray Trends (NEXT), but would be collected through the MODS system, rather than by local inspections.

The potential value of such data would be to: (a) encourage the use of radionuclides which deliver less dose per study; (b) evaluate the impact of new products on the practice of nuclear medicine; and (c) provide a basis for governmental evaluation of existing programs and planning for new ones. For this data to be useful, a collection system is needed which would permit analysis and comparison, not only with previous data, but with models accepted by experts in the medical practice. In addition, the system should include appropriate feedback to the users.

It was pointed out that the mere collection of data and establishment of a national average population dose would do little to reduce that dose; however, these would provide a mechanism for determining current trends. Such information would enhance the effectiveness of nuclear medicine procedures while minimizing the population dose.

RECOMMENDATIONS

1. It is recommended that the Conference Executive Committee establish a task force composed of members from the Conference, Bureau of Radiological Health, Bureau of Drugs, and others with particular needs in this area to promote the development of a reliable data collection system for nuclear medicine practices. The task force should report the development cost, format of the system, and its applicability to the needs of both State and Federal agencies.

2. Concurrently with the development of the data collection system, the task force should address itself to the development and implementation of the methodologies to reduce unnecessary radiation, including associated equipment used in nuclear medicine procedures.

WORKSHOP NO. 8

STATE CREDENTIALING PROGRAM FOR RADIATION ALLIED HEALTH OPERATORS

Larry Lloyd, Chairman, Montana
Dennis R. Hohn - Montana
Dr. H. Pagan-Saez - Puerto Rico
Henry Copeland - Georgia
Darrell Hocken - Oregon
Corrine Larson - Minnesota
Don Hughes - Kentucky
Ray McCandless - Vermont
O. Doc Gibbons - New Jersey
Thomas Anamizu - Hawaii

Gene Moss - NIOSH
Steve Fritz - SIU Medical School
Joe Capella - Florida Community College
Virginia Milligan - ASRT
Ray Horner - ASRT
Norbert Heib, Jr. - BRH

The following concepts should be considered in the development of goals for any credentialing system (This list is not meant to be completed):

- Recognition of the existence of an occupational family of groups involved in the application of ionizing radiation to humans.
- Credentialing standards based upon performance criteria.
- Credentialing expiration dates with specific renewal requirements (continuing education seems to be the most acceptable.
- A form of limited credentialing.
- Encouragement of State use of uniform national guidelines.
- Credentialing requirements allowing for multiple entry and transfer routes to the occupations based upon established prerequisites.
- Provision of State mechanisms for reciprocity.
- Uniform national testing criteria.
- Grandfathering mechanisms.
- Conditions for complaint followup, disciplinary actions, revocations, and so forth.

RECOMMENDATIONS

The Workshop recommends that the Conference:

1. Endorse FDA's Bureau of Radiological Health proposed activites in the area of development of national uniform guidelines for the qualifications of radiation operators.
2. Nominate representatives to the proposed Advisory committees of the FDA's Bureau of Radiological Health.
3. Establishing a workshop at the ninth Annual Meeting to consider the need for credentialing users of nonionizing radiation.
4. Form a Task Force on the credentialing of operators using sources of ionizing radiation. The membership on this Task Force should not be limited to States having credentialing authorities.

Purposes and Objectives

The purpose of the Task Force will be to develop recommendations on the design of a credentialing system for radiation operators. The objectives of the Task Force should include the development of a conceptual framework for a credentialing system including but not limited to:

1. Determing purposes, goals, and relationships in a credentialing system and define its options.
2. Evaluating the advantages and disadvantages relating to existng and the States.
3. Identifying the occupational groups which should be included in the credentialing system.

In addition to the above objectives, the Task Force should:

1. Develop and supplement procedures to be used in obtaining State comments and reviews of the suggested national guidelines.
2. Propose a mechanism to collect and analyze data that could be used to monitor the radiation protection practices of radiation personnel.

REPORT ON RESOLUTIONS

Gerald S. Parker, Chairman

Because of their complexity, the resolutions will be transmitted to the membership through the mail for a mail vote. One resolution was withdrawn and I will now read the resolution that passed the Conference:

WHEREAS regulations are constantly under revision,

WHEREAS there is a tendency to perpetually add to regulations,

WHEREAS seldom is any authorization which no longer having beneficial use removed from regulations,

WHEREAS regulations must be continually justified to those being regulated and the general public, and

WHEREAS a specific license can be used for those exceptional situations where the use is justified on a case-by-case basis,

THEREFORE BE IT RESOLVED that the Conference petition the NRC to review its current regulations and purge those portions of the regulations not in step with present day radiation protection philosophy.

Two examples of the need for review are the general license of source material to physicians and pharmacists, and the Exemption from Licensing of scandium-46 for well logging.

In addition to the resolutions that were submitted to the Resolutions Committee, the Conference considered three other resolutions. Two of these will be considered by the Executive Board in its deliberations this afternoon, this evening, and tomorrow. One of these resolutions passed the Conference during its meeting yesterday.

WHEREAS the technical assistance activities of the Environmental Protection Agency, including analytical laboratory support and radiation monitoring has been of immeasurable help to radiation control programs of the States, thereby benefitting the public health of the nation, and

WHEREAS the Environmental Protection Agency has been directed to reduce or eliminate the provision of such a system to the States,

BE IT THEREFORE RESOLVED that the President and Congress of the United States be made aware of the concern of the Directors of State radiation control programs in the loss of such technical assistance and that the President and Congress be encouraged to make every effort to restore and perhaps increase this important and necessary function of the Environmental Protection Agency as one means to insure the continued protection of the Nation's public health and safety through cooperative State/Federal radiation control programs.

These two resolutions have been passed and the others that will be considered will be submitted to the appropriate authorities.

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS
EXECUTIVE COMMITTEE REPORT

Gerald S. Parker, Chairman

The Executive Committee has gone through its usual marathon of meetings, and their meetings are continuing. We will be meeting this afternoon, this evening, and all day tomorrow. We started the meeting last Saturday night, and continued all week, during all kinds of weird hours, starting at 7:00 a.m. and finishing at midnight. Thank the Lord for the oxygen and digitalis which was available to us, because I think those are the only things that saved us this year.

This Conference owes a debt of gratitude to Bob Will who was Captain of the ship through this trying and difficult period. I must disagree with Bob, however, on his comments about surviving; on the contrary, we more than survived. We matured, blossomed, and made great progress in our quest for quality, while ascending new horizons. As a result of meetings this week, we are able to report to you that the Executive Board will be able to continue the great progress made during Bob Will's administration.

Dr. Claire Nader suggested that we meet with physicians to work out our mutual problems. At a meeting with three members of the American College of Radiology, the day before Dr. Nader made her comments, we discussed the possibility of having a 2-hour no holds barred meeting between State radiation control personnel and representatives of the State Radiology Societies. I am happy to be able to report to you that such a session will take place during the Seattle meeting. The cooperation now developing between the regulators and the radiologists must continue if we are to make any progress in our campaign to Save-A-Rad.

The Executive Board, in discussions with various Federal agencies, agreed to take many new steps. We will set up an overall cabinet group responsible for a single area of concern. This first group will involve themselves with problems encountered of the use of radiation in the healing arts. I am pleased to announce that Alice Dolezal has accepted the responsibility of chairing this cabinet. She will be contacting you so that you will be able to help us in defining and solving some of the problems encountered in the use of radiation in the healing arts.

The Board has requested that FDA do some research and development work for dosimetry for CT scanning, so that we, as radiation control people, can help other State regulators in assessing the role of CT scanners in the armamentarium of health care. FDA has also agreed to prepare some overall guidelines on mammography, in addition to the work that they are already doing on dosimetry.

In our meetings with the National Bureau of Standards, we agreed mutually that it would be beneficial if NBS would help the States develop technical specifications for laboratory and portable survey equipment. Many of us find ourselves in the position of preparing bid specifications which do not contain sufficient detail so that we do not get the latest equipment. With money being so tight at the State/Federal level, it behooves all of us to take care before spending money for equipment. With the help of NBS, we hope to be able to supply each State with specification for all types of laborabory and survey equipment.

In our meetings with EPA, we asked them to help us solve problems encountered in laboratories. The data recently published by Jarvis, et al. from the Las Vegas laboratory indicated that quality assurance is lacking in some radiation environment laboratories. During the coming year, we will be working closely with EPA to develop methods so that there can be some assurance that the laboratory results that we receive are accurate. It is very difficult for State regulatory people to make decisions if they cannot rely on the results that they are receiving from the laboratories.

The Board was disturbed about possible cutbacks in EPA's technical assistance activities to the States. You have heard the resolution. We will transmit that resolution to the Congress and to the President.

In our meetings with NRC, we rediscussed for the umpteenth year in a row emergency planning. Some progress has to be made in this area, and we will attempt to do that during this coming year.

This coming year will be a challenging one. On behalf of the Executive Board, I accept these new challenges; however, I and the members of the Board cannot carry out our duties without the cooperation of all of the members. Please help us by being more responsive to our letters, as we attempt to plan for and assuring radiation protection. To paraphrase the late President Kennedy, do not ask what the Conference can do for you, ask what you can do for the Conference. And what you can do is answer our letters. We, on the other hand, will be more responsive to your requests and ideas.

SUMMATION AND CLOSING REMARKS

Gerald S. Parker
Chairman, Conference of Radiation Control Program Directors

Sheldon A. Schwartz
Senior State Relations Officer
Office of International and State Programs
U.S. Nuclear Regulatory Commission

Robertson J. Augustine, Ph.D.
Regional Liaison
Office of Radiation Programs
Environmental Protection Agency

James W. Miller, D.D.S.
Director, Radiation Operations Staff
Division of Field Operations
Executive Director of Regional Operations, FDA

MR. PARKER: Now we come to the summation and closing remarks. I always look forward to this session and the remarks of our Federal liaison people who accurately sum up what has happened during this week. I would now like to ask Dr. Miller, Dr. Augustine, and Mr. Schwartz to come forward.

MR. SCHWARTZ: You are right; it has been a long week. At this point in time, I think that my receiving and sending systems, along with my logic circuits, have failed completely, or are on the verge of collapse. I expect that many of you are suffering from the same phenomenon, which I have diagnosed as "CRCPD," or "Continuous Reactivity Causing Perception Deterioration." I think that during the week, as I traveled through the hallways from meeting to meeting, I must have traveled as many miles as Governor Walker did in trying to find the bounds of Illinois.

My summation and closing remarks, therefore, will not be penetrating, nor representative of what went on here during this week. They will, therefore, be very brief.

I do not know if it was the pervasive influence of this location--"The Land of Lincoln"--but at this annual State and Federal "roasting," honesty did prevail, irrespective of whether you were the roastee or the roastor. I believe that this is the real value of this meeting--the jousting and informational sessions that are constantly going on, either in the plenary sessions, the workshops, the side meetings, or the one-to-one relationships in the halls and the nooks and crannies around the motel. I saw a lot of nose-to-nose finger waving, arm waving, and a lot of slapping of foreheads during this meeting.

Communication of this sort is good for all of us. It gives us an opportunity to listen and be listened to, and if there is support for our ideas, we hear about it. If there is no support, we hear about that as well; but generally in an atmosphere of honest disagreement, and not as adversaries.

We have common goals, and for a variety of reasons, choose different routes to achieve them. My colleagues in the NRC, who attended this meeting, share my view that this was a highly productive and professional meeting. I think the workshop reports that we have just heard bear this out, and I guess I can remember the first meeting that I attended of the Conference in San Antonio; a lot of the workshop reports were given from notes on cocktail napkins, and I think this year you can see that professionalism has come to play in the Conference.

If it were not for your cooperation, the excellent planning by your past Chairman, Bob Will, and the Executive Board, and the execution by Phil Brunner and his staff, it could not have happened.

I congratulate all of you for a very fine meeting. In summary, then, I look forward to working with each of you throughout this coming year, as well as your new Executive Committee, and particularly Gerry Parker, for whom I personally have a very warm feeling and lot of respect.

DR. AUGUSTINE: I am approaching the microphone with kind of mixed feelings, especially about Gerry Parker. As you know, there are a lot of inside jokes and inside stories in this organization, and if I were to relate some of these, only three-fourths of you would laugh; the other fourth would not know what I was talking about.

One thing that I will refer to is the fact that Gerry Parker is a great singer. Most of you do not know this; you have not seen him perform this role, but we did catch him in the act one time, and I have a set of photographs which document his singing ability.

I think that the Eighth Annual National Conference on Radiation Control has been a good one. You have all worked hard; you have all played hard; some of you have worked harder than others, and some of you have played harder than others. But I think that it is this combination of hard work and hard play which kind of distinguishes this technical meeting from other technical meetings. The meeting also allows crossing boundaries between States and Federal agencies, or between one Federal agency and another Federal agency, and you really don't worry about the fact that you are crossing boundaries; you are all here for one purpose.

I would like for you to reflect for a moment on the theme of the meeting. If some or you did not know it, it appeared on the cover of your program. It is called "Radiation Benefits and Risks: Facts, Issues, and Options." I would like for you to consider in your minds the technical program this week, and I think you can summarize in your own mind the fact that the meeting was directed towards the theme. You will find that the program covered a wide range of radiation issues and problems, both in size and in complexity. For example, the radiation issues ranged from very small things, such as the main emphasis of the diagnostic radiology portion of this meeting, to large things like a major share of a real estate in Florida. I recognize that I am mixing apples and oranges in this example.

Getting back to the technical side, it is interesting that the risk estimates for most of the problems that we have considered--the small ones and the large ones--primarily, the risk estimates are based on the same collection of technical data and scientific opinion, and that is the report on the Biological Effects of Ionizing Radiation. I think it is that fact that draws this organization together; we are all interested in the same goal, no matter what our current topic of interest is, whether it is contamination of real estate, or x-raying small things.

We appreciate the fact that the number of you State people were concerned enough with the proposed cutback in the EPA State assistance activities to individually contact the right people. We also appreciate very much the fact that the Conference as a whole is concerned with its cutback in State assistance activities, and that you have passed a resolution which hopefully will bring attention in the right places.

In summary, on behalf of EPA, including our Regional Representatives who are here, our Headquarters people, Dr. Rowe, who had to go back on Wednesday, I would like to thank the Conference for the opportunity of working with you, not only at the Conference meeting, but throughout the year, and the work done in the Task Forces and many effective committees. We feel that this is a much better way to share revenue; that is, by coming to the Conference that serves as a two-way street. I think we get back much more from the Conference and from the States than it costs us to put in to the pot to run the Conference.

DR. MILLER: It gives me "great pleasure" to have the opportunity at this closing session to reflect for a few moments on the meeting and the activities of the Conference since our get-together last year at Hyannis. This has truly been an exceptional meeting; like fine wines, our meetings seem to get better each year. This is not by accident but the result of a lot of hard work by your host and his entire staff, the FDA Regional Office, your Executive Committee, the sponsoring Federal agencies, the speakers and clinicians; but most of all, it is your interest and dedication which makes this meeting and the Conference a success.

The theme of this year's meeting aptly describes something we are involved with each day as we carry out our responsibilities of protecting the public's health. We must continually evaluate the hazards of radiation in light of the many benefits derived from its prudent use. This is not always easy; in some instances it is almost impossible. We must, however, weigh the facts in light of current knowledge, examine the issues, and select our best options. This meeting is a necessary ingredient to the process of making the best selection. What is obvious to all who have an interest in radiological health is that this is not just a Federal-State effort, but includes professional user groups, industry, and the consumer. We know radiological health requires a team effort. It is through our annual meeting with individuals representing these various groups that we improve communications through a discussion of problems or issues and keep the team concept viable. Radiation control may be our name but radiation protection is our game. In the end we must be certain that the benefits of radiation to the public clearly outweigh and hazards associated with its use.

During this meeting we continued the practice of looking at issues from several different points of view. I thought all the papers were excellent. The State presentations merit special mention. As usual, they were informative and first rate. The accomplishments of the Task Forces which have been at work all year have been impressive. The table clinics were super and the most we have ever had. The Workshops were once again productive and conclusive. This truly has been a worthwhile week. So, on behalf of the FDA, especially the Office of the Commissioner, the Bureau of Radiological Health, and the Executive Director of Regional Operations, I want to compliment and thank you all for your contribution to this most informative and productive 8th meeting. I would like to add our thanks to those already expressed by Bob Augustine and Shelly Schwartz; to Phil Brunner, his staff, and the Illinois Department of Health; and Jim Kraeger, FDA Region IV, for the great job they did in making this another memorable annual meeting.

MR. PARKER: I have already reported on the Executive Board's activities and accomplishments in my previous remarks. The preceding three speakers have given an accurate summary of what occurred at this meeting so I do not believe that it is necessary to add anything.

As Jim Miller would say, this has truly been a fantastic meeting. But to put on a meeting such as this takes a lot of blood, sweat, and tears. On behalf of the Conference of Radiation Control Program Directors and the three sponsoring agencies, I would like to thank Carol and Phil Brunner for the wonderful arrangements and social activities. I would also like to thank members of Phil's staff: Linda Raye, Maury Neuweg, Paul Eastvold, Caroline Handy, Barbara Kerns, Dennis Deane, Steve Dennis, Chuck Bench, Anita Stanley, John Newsome, Jim Blackburn, Marty Simmon, and the public information people, Mary Huck, and Dick Ridgway, and finally, our photographer, Marty Wilde.

Art Lazell, FDA/BRH, for his valuable work in the public relations area and Chuck Coyle, FDA/BRH, for his valiant efforts in getting the proceedings published should receive our recognition. The Executive Board wishes to thank Jean McGuire for making their tasks easier by being their right hand person during this meeting.

Finally, I would like to introduce the new officers of the Conference: our Charman Elect, Dale McHard from Oklahoma; our new Board Member at Large, Phil Brunner.

The Ninth Annual National Conference on Radiation Control will take place in Seattle, Washington from June 19-24, 1977. I look forward to seeing all of you at that time.

The Eighth Annual National Conference on Radiation Control is adjourned.

* U. S. GOVERNMENT PRINTING OFFICE : 1977 241-189/353

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Accession No.

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U.S. Department of Health, Education, and Welfare, PHS,FDA, Bureau of Radiological Health - HEW Publication (FDA) 77-8021 (April 1977) 428 pp. (limited distribution).

ABSTRACT: This publication contains the proceedings of the 8th Annual National Conference on Radiation Control--Radiation Benefits and Risks: Facts, Issues, and Options, held May 2-7, 1976, in Springfield, Illinois. Sponsors were the Conference of Radiation Control Program

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KEYWORDS: Atomic Energy Act; Bonding; Communications; Contamination; CT Scanners; Diagnostic Radiology;Emergency Response; Environment; Guidelines; Mammography; Manufacturing; Medical Accelerator; NEXT; Nuclear Power; Nuclear Medicine; Perpetual Care; Personnel; P.L. 90-602; Protection; Quality Assurance; Radiation Control; Radioactive Materials; Regulations; Soil; Standards; State Credentialing; Transportation; Waste Management; X Ray.

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FDA 76-8048	Radiation Protection During Medical X-Ray Examinations - Part 4, Biological Effects of X Rays (National Audiovisual Center (GSA), Washington, D.C. 20409, $48.00).
FDA 76-8049	Radiation Protection During Medical X-Ray Examinations - Part 5, Gonad Shielding in Diagnostic Radiology (National Audiovisual Center (GSA), Washington, D.C. 20409, $39.00).
FDA 76-8051	Directory of Personnel Responsible for Radiological Health Programs (superseded by FDA 77-8016).
FDA 76-8052	Nationwide Evaluation of X-Ray Trends (GPO 017-015-00110-5, $0.35).
FDA 76-8053	The Double-Edged Sword (Flyer).
FDA 76-8054	Specific Area Gonad Shielding - Recommendation for Use on Patients During Diagnostic X-Ray Procedures (GPO 017-015-00111-3, $0.45) (PB 258 039/AS, mf only).
FDA 76-8055	Diagnostic Ultrasound: A Review of Clinical Applications and the State of the Art of Commercial and Experimental Systems (GPO 017-015-00112-1, $1.45) (PB 258 237/AS, mf only).
FDA 76-8056	CSU-FDA Collaborative Radiological Health Laboratory Annual Report 1975 (PB 257 937 AS, $6.75, $3.00 mf).
FDA 76-8058	Quadrennial Report of the Division of Biological Effects (PB 258 436/AS $6.75).
FDA 76-8061	Uranium in Dental Porcelain (GPO 017-015-00113-0, $1.00) (PB 259 624/AS, mf only).
FDA 77-8001	BRH Routine Compliance Testing for Diagnostic X-Ray Systems (PB 261 082/AS, $7.75).
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